

2023-2024

中国医药创新促进会

协会会刊

China Pharmaceutical Innovation
and Research Development Association
Journal

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会长寄语

MESSAGE FROM CHAIRMAN OF PhIRDA



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岁序常易，华章日新。辞旧迎新之际，我们豪情满怀拥抱未来。

回溯2023年，硕果累累、步履坚实。习近平总书记强调，生物医药产业是关系国计民生和国家安全的战略性新兴产业，要加强基础研究和科技创新能力建设，把生物医药产业发展的命脉牢牢掌握在我们自己手中。这一年，药促会全体同仁精诚协作、务实笃行，精准“把脉”国家重大战略，产业模式创新、产品创新、监管创新同步发力，高质量完成多项国家政府部门委托研究专题，高效推动ICH指导原则在中国落地转化实施，积极参与《药品管理法实施条例》《科技伦理审查办法》等重要政策法规制修订，成功举办上海合作组织医药合作发展大会、中国医药创新与投资大会、中国国际生物医药大会等国内国际交流活动，迸发出促进我国生物医药产业高质量发展的强大动能。

展望2024年，前路广阔、行则将至。今年，中国将接棒担任上海合作组织轮值主席国，带来提升国际医药创新领域话语权和国际竞争力的发展契机。国家所需就是目标所向，作为药促会新一任年度会长，我愿同各位一道，化信任为责任，变压力为动力。面向生物医药强国建设目标，深入开展药品创新支付体系建设、产业创新激励政策先行先试等政策研究，持续跟进《医疗保障法》《医疗器械管理法》等重大立法制修订，充分发挥高端智库作用，促进国内生物医药创新生态加速形成。面向全球产业前沿，推动与上合组织国家深入合作，促成医药企业高级别代表团出访，办好中国医药创新与投资大会、中国罕见病大会等品牌活动，开创合作共赢新局面。面向会员单位发展需求，保障分支机构换届工作有序进行，丰富业务交流活动，为医药产业各创新主体提供更多价值服务。

众力并，则万钧不足举。在新的一年里，让我们以人民健康为念、以医学发展为怀，紧跟国家发展战略，持续提升科技创新力，推动生物医药产业创新和可持续发展取得更多丰硕成果，更好为我国经济社会发展和人民群众健康保驾护航！

会长寄语

MESSAGE FROM CHAIRMAN OF PhIRDA

Innovation Inspires Development Healthcare for One and All

The passage of time witnesses changes, and each day brings new achievements. As we bid farewell to the old days and welcome the new, we embrace the future with great enthusiasm.

Looking back at the year 2023, it was a productive year with solid progress. President Xi Jinping emphasized that the biopharmaceutical industry is a strategic emerging industry that is related to comprehensive development, people's livelihood, and national security. It is necessary to strengthen basic research and technological innovation capabilities and firmly hold the lifeline of the development of the biopharmaceutical industry in our own hands. In this year, colleagues of the China Pharmaceutical Innovation and Research Development Association (PhIRDA) worked together with team spirit and dedication, precisely "diagnosed" major national strategies, and made parallel efforts in innovation of industrial model, manufacture, and regulation. They completed multiple research topics entrusted by national government departments with high quality, efficiently promoted the implementation of ICH guidelines in China, actively participated in the revision of important policies and regulations such as the "Regulations on the Implementation of the Drug Administration Law" and the "Regulations for Ethical Review of Science and Technology", and successfully held domestic and international exchange activities such as the Shanghai Cooperation Organization Pharmaceutical Cooperation Development Conference, China BioMed Innovation and Investment Conference, and China International BioPharma Conference, which demonstrated a strong driving force for promoting the high-quality development of China's biopharmaceutical industry.

Looking forward to 2024, the road ahead is broad and progress will be made if we make efforts. This year, China will take the rotating chairmanship of the Shanghai Cooperation Organization, bringing opportunities for enhancing power of China voice and international competitiveness in the field of medical innovation. Nation's need is our goal, and as the newly appointed PhIRDA Chairman of the year, I am willing to work together with colleagues from the industry to turn trust into responsibility and transform challenges to motivation.

Focusing on the goal of building a powerhouse in the biopharmaceutical industry, we will carry out in-depth research on policy such as the construction of a drug innovation payment system and the initiatives of industrial innovation incentives. We will actively follow up on major legislative modifications, such as the Medical Insurance Law and the Medical Device Management Law, and fully leverage the role of high-end think tanks to accelerate the formation of a domestic biopharmaceutical innovation ecosystem.

Facing the forefront of the global industry, we will deepen cooperation with countries in the Shanghai Cooperation Organization, facilitate high-level pharmaceutical delegation visits, organize events such as the China BioMed Innovation and Investment Conference and the China Conference on Rare Diseases, and to develop win-win partnerships.

In response to the development needs of membership organizations, we will ensure the orderly transition of branch institutions, enrich business exchange activities, and provide more value-added services to all innovative entities in the pharmaceutical industry.

When we have the joint efforts, then no weight is too heavy to lift. In the new year, let us prioritize the health of the people and focus on the development of medicine, closely follow the national development strategy, continuously enhance technological innovation, and promote greater achievements in the innovation and sustainable development of the biopharmaceutical industry. To facilitate the economic and social development of our country and the health of the people!

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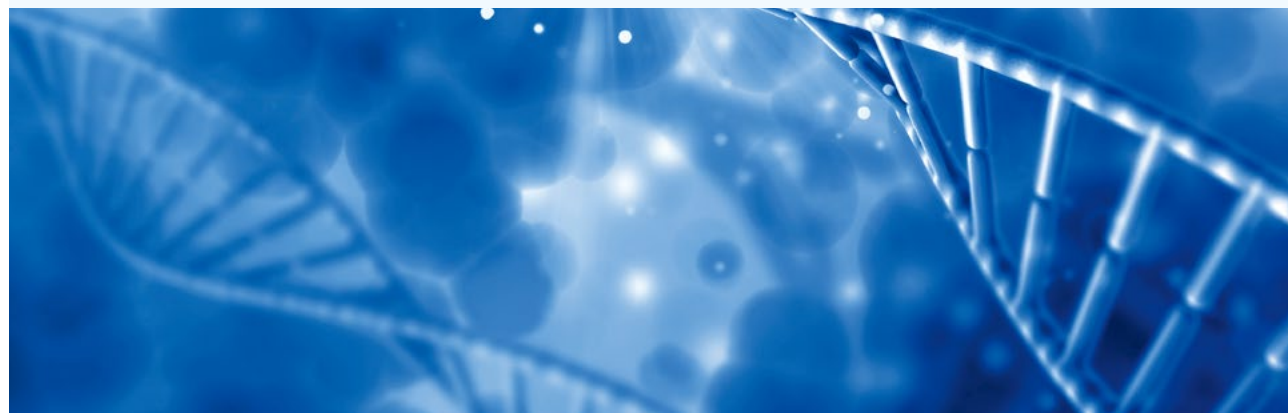
中国医药创新促进会简介

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

中国药促会秉承“创新、产业化、国际化”的宗旨，以临床需求为导向，长期致力于“产学研用资”紧密结合，促进医药行业创新发展，已经成为集医药创新研发型企业、科研机构、临床研究机构、创新服务机构和医药投资机构所组成的医药创新产业化促进平台，目前有会员单位186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、医药数字化及创新疗法、创新医疗器械专业委员会，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架构，并作为国际药品制造商协会联合会（IFPMA）的成员继续拓展国际交流渠道。

中国药促会工作内容主要包括：一是，开展医药政策研究，为我国医改事业、完善药械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！



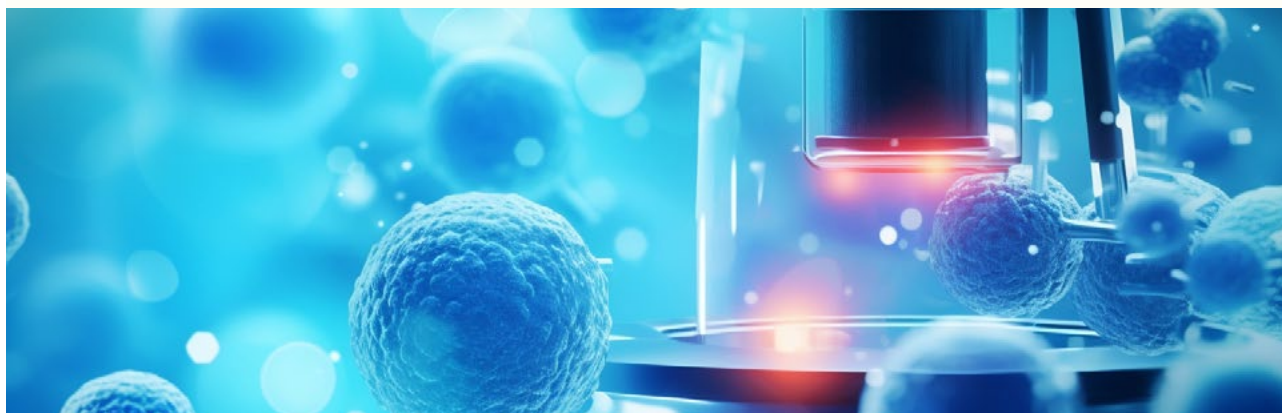
Brief Introduction to PhIRDA

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.

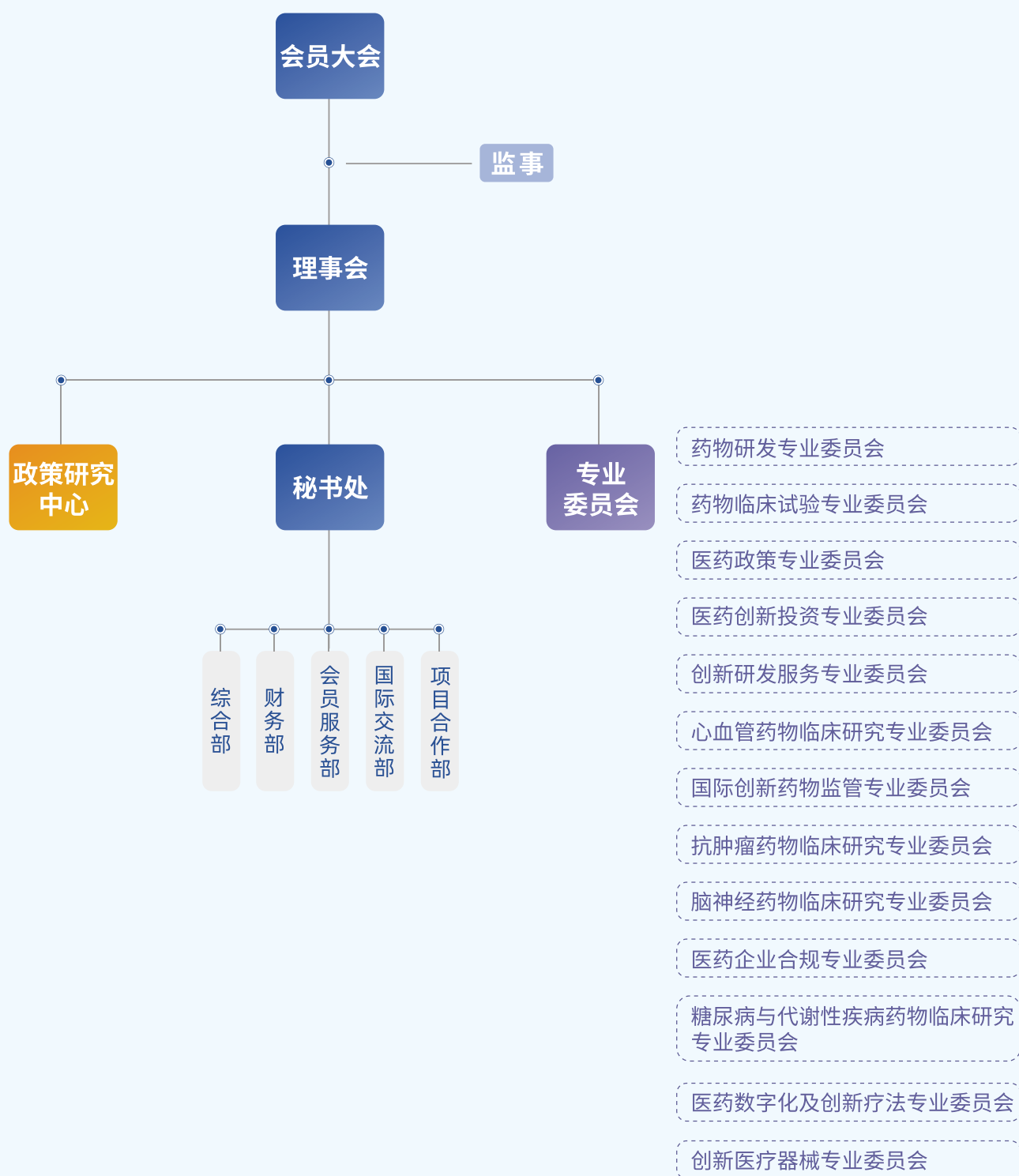
PhIRDA has been exerting great effort on “academia-industry-investment collaboration”, which centers on the principle of “innovation, industrialization, internationalization”, and persists in innovation to achieve unmet clinical requirements. As a platform facilitating the industrialization of pharmaceutical innovation, PhIRDA currently has 186 members mainly consisting 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 Drugs, Digital Medicine and Innovative Therapy, Innovative Medical Devices, 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.

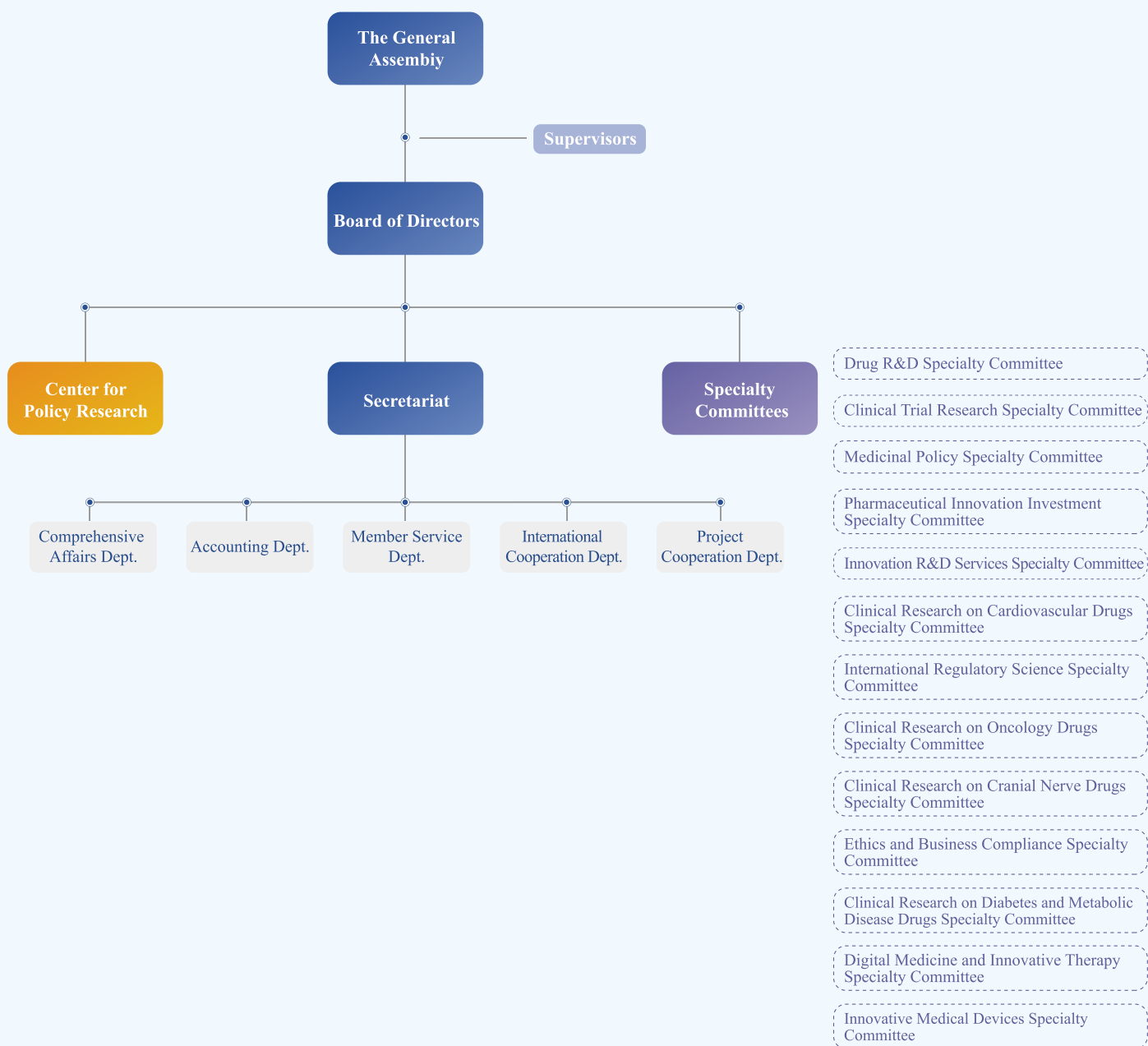
PhIRDA will center on our principle, continuously expand services, build a bridge between the government and our members, maintain legitimate rights and interests of members, strengthen self-discipline, promote healthy development of Chinese pharmaceutical industry, making constant contributions to the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



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



陈凯先 主任
中国科学院院士

Chen Kaixian, Chairman
Academician of Chinese Academy
of Sciences



曹雪涛 委员
中国工程院院士

Cao Xuetao, Member
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

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



王广基 委员
中国工程院院士

Wang Guangji, Member
Academician of Chinese Academy
of Engineering



葛均波 委员
中国科学院院士

Ge Junbo, Member
Academician of Chinese Academy
of Sciences



魏于全 委员
中国科学院院士

Wei Yuquan, Member
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

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



程 京 委员
中国工程院院士

Cheng Jing, Member
Academician of Chinese Academy
of Engineering



王晓东 委员
中国科学院外籍院士

Wang Xiaodong, Member
Foreign Academician of
Chinese Academy of Sciences



王松灵 委员
中国科学院院士

Wang Songling, Member
Academician of Chinese Academy
of Sciences



丁文江 委员
中国工程院院士

Ding Wenjiang, Member
Academician of Chinese Academy
of Engineering



岳建民 委员
中国科学院院士

Yue Jianmin, Member
Academician of Chinese Academy
of Sciences



樊 嘉 委员
中国科学院院士

Fan Jia, Member
Academician of Chinese Academy
of Sciences



王 锐 委员
中国工程院院士

Wang Rui, Member
Academician of Chinese Academy
of Engineering



李校堃 委员
中国工程院院士

Li Xiaokun, Member
Academician of Chinese Academy
of Engineering

会领导介绍

INTRODUCTION TO PhIRDA LEADERSHIP



会领导介绍

Introduction to 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,
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
兼首席执行官

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 & CEO, Sincere
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.



李 佳

2022-2023年度会长
中国科学院上海药物研究所所长

Li Jia

Annual Chairman 2022-2023
Director, Shanghai Institute of Materia
Medica, Chinese Academy of Sciences

现任会领导 Current Leadership of PhIRDA



张抒扬 会长
北京协和医院院长

Zhang Shuyang, Chairman
President, Peking Union Medical
College Hospital



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



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
兼首席执行官

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



刘殿波 副会长
绿叶生命科学集团董事局主席

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



任晋生 副会长
先声药业集团有限公司董事长
兼首席执行官

Ren Jinsheng, Vice President
Chairman & CEO, Sincere
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.



李 佳 副会长
中国科学院上海药物研究所所长

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



柯尊洪 副会长
成都康弘药业集团股份有限公司
董事长

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



闫凯境 副会长
天士力医药集团股份有限公司
董事长

Yan Kaijing, Vice President
Chairman of the Board, Tasly
Pharmaceutical Group Co., Ltd.



赵 勇 副会长
上海医药党委副书记、副总裁

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



吴晓滨 副会长
百济神州全球总裁兼首席运营官

Wu Xiaobin, Vice President
President and Chief Operating
Officer, BeiGene



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

Introduction to Specialty Committees



专业委员会介绍

中国药促会目前已成立13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,为会员单位和整个药械产业提供更多元的价值服务,受到社会各界广泛关注和好评。

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。

医药数字化及创新疗法专业委员会旨在通过开展政策研究、促进产融结合、搭建跨界交流合作平台等方式,推动中国医疗数字化创新产业蓬勃发展。

创新医疗器械专业委员会旨在为行业“政、产、学、研、用、医”搭建良好沟通交流平台,推动创新医疗器械行业监管、技术研发、临床应用与成果转化。

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 to Specialty Committees

At present, PhIRDA has established 13 Specialty Committees. Leveraging the resources of experts and members, PhIRDA has conducted a great deal of effective work in areas including 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. The committees aim to provide more diversified and valuable services for PhIRDA members and pharmaceutical industry, obtaining widespread attention and acclaim from various sectors of society.

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 Drugs Specialty Committees, and Clinical Trial Research Specialty Committee, aim to promote the relevant abilities by enhancing the research on innovative drug R&D and clinical trial.

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

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

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

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

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

Digital Medicine and Innovative Therapy Specialty Committee aims to conduct policy research, foster integration of financing with the industry, and establish cross-border platforms for exchanges and cooperation to promote the flourishing innovative development of the pharmaceutical digitalization in China.

Innovative Medical Devices Specialty Committee aims to establish a platform for effective exchanges among the government, industry, academia, research, application, and clinical, to promote regulatory supervision, technological R&D, clinical applications, and transformation of outcomes in the innovative medical devices 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.

第四届药物研发专业委员会 The 4th Drug R&D Specialty Committee



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董事长兼总经理

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



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副院长

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



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安全评价研究中心主任、研究员

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Professor & Director of Center for
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Shanghai Institute of Materia Medica,
Chinese Academy of Sciences



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University



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联合创始人兼首席战略官

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Co-founder and Co-Chairman of
Hillgene Biopharma & Co-founder
and Chief Strategic Officer of
ClinChoice Inc.



房健民 副主任委员

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首席执行官兼首席科学官

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深圳微芯生物科技股份有限公司
研发中心主任兼药政事务与药物
警戒部负责人

Wang Xinhao, Secretary-General
Director of R&D Center, Head
of Regulatory Affairs and
Pharmacovigilance Dep, Shenzhen
Chipscreen Bioscience Co., Ltd.

第四届药物临床试验专业委员会 The 4th Clinical Trial Research Specialty Committee



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北京大学临床药理研究所所长

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



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医学伦理委员会副主任委员，药物
I期临床试验研究室名誉主任

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University School of Medicine,
Director of Clinical Trial Institution
Office, Beijing Tsinghua Changgung
Hospital

第四届医药政策专业委员会 The 4th Medicinal Policy Specialty Committee



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Professor & PhD Supervisor, School of Public Health, Fudan University



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Secretary of Party Committee & Vice President, Sincere Pharmaceutical Group

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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海捷投资控股集团首席合伙人

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中国私募股权投资联席总裁

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Managing Director, Co-Head of
China Private Equity, Warburg
Pincus



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国寿股权投资管委会主任

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Head of Management Committee,
China Life Private Equity Investment
Co., Ltd.



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CIO, Huagai Healthcare Fund



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General Manager, China Merchants
Health Care Holdings Co., Ltd.



陈 侃 秘书长

启明创投合伙人

Chen kan, Secretary-General
Partner of Qiming Venture Partners

第三届创新研发服务专业委员会 The 3rd Innovation R&D Services Specialty Committee



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董事长兼执行总裁

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President & CEO of Shanghai LIDE
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ClinChoice昆翎全球董事长兼
首席执行官

Zhen Ling, Vice-Chairman
Global Chairman & CEO, ClinChoice



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创始人、董事长

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



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创始人、首席执行官

Ma Jian, Vice-Chairman
Co-Founder, CEO of XtalPi Inc.



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浙江九洲药业股份有限公司总裁

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President of Zhejiang Jiuzhou
Pharmaceutical Co., Ltd.

第二届心血管药物临床研究专业委员会

The 2nd Clinical Research on Cardiovascular Drugs Specialty Committee



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上海复旦大学附属中山医院
心内科主任

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



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北京大学第一医院心内科首席专家

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



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广东省人民医院首席专家

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



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西安交通大学第一附属医院
心血管病医院院长

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



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常务副院长

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Hospital, Capital Medical University



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Director of Cardiology Department,
Peking Union Medical College Hospital



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附属协和医院副院长

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Vice President of Union Hospital,
Tongji Medical College, Huazhong
University of Science and
Technology



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中国科学院上海药物研究所
学术所长

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



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上海复旦大学附属中山医院
心内科副主任

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



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南京医科大学第一附属医院
心血管内科主任

Kong Xiangqing, Vice-Chairman
Director of Cardiology Department,
The First Affiliated Hospital with
Nanjing Medical University



张 岩 副主任委员兼秘书长

北京大学第一医院心血管内科
副主任（主持工作）

Zhang Yan, Vice-Chairman & Secretary-General
Deputy Director of Cardiology Department, Peking
University First Hospital (presiding over work)

第二届国际创新药物监管专业委员会 The 2nd 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

He Ruyi, Chairman

CMO of RemeGen, CMO of SDIC, Former Chief Scientist of Center for Drug Evaluation, CFDA



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深圳埃格林医药董事长

Du Tao, Chairman-Elected

Chairman of Shenzhen Evergreen Therapeutics Co., Ltd.



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美国安诺波特律师事务所驻上海代表处管理合伙人

Chen Shaoyu, Vice-Chairman

Managing Partner of Arnold & Porter LLP Shanghai Rep. Office



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深圳埃格林医药有限公司首席执行官

Du Xin, Vice-Chairman

CEO of Shenzhen Evergreen Therapeutics Co., Ltd.



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上海君实生物副董事长

Li Ning, Vice-Chairman

Vice Chairman of Shanghai Junshi Biosciences Co., Ltd.



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浙江海昶生物医药有限公司总裁

Zhao Xiaobin, Vice-Chairman & Secretary-General

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

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



秦叔逵 顾问
南京天印山医院院长

Qin Shukui, Counselor
Dean of NanJing TianYinShan
Hospital



孙飘扬 顾问
江苏恒瑞医药股份有限公司董事长

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



孙 燕 顾问
中国工程院院士

Sun Yan, Counselor
Academician of the Chinese
Academy of Engineering



吴一龙 顾问
广东省人民医院终身主任

Wu Yilong, Counselor
Tenured Professor & Director of
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李怡平 Li Yiping	上海药明巨诺生物科技有限公司联合创始人、董事长兼首席执行官 Co-founder, Chairman & CEO, JW Therapeutics (Shanghai) Co., Ltd.
崔霁松 Cui Jisong	北京诺诚健华医药科技有限公司董事会主席兼首席执行官 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.
谢 东 Xie Dong	前沿生物药业(南京)股份有限公司董事长、首席科学家 Chairman of the Board & CSO, Frontier Biotechnologies Inc.
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.
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
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.
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 北京五和博澳药业股份有限公司董事长
Huang Yuesheng Chairman of the Board, Beijing Wehand-Bio Pharmaceutical Co., Ltd.
- 史晓峰 远大医药(中国)有限公司董事长
Shi Xiaofeng Chairman of the Board, Grand Pharma (China) Co., Ltd.
- 吕向阳 来凯医药科技(上海)有限公司创始人、董事长兼CEO
Lyu Xiangyang Founder, Chairman of the Board & CEO, Laekna Therapeutics Shanghai Co., Ltd.
- 向宇 上海琅钰健康科技(集团)有限公司首席执行官
Xiang Yu CEO, RareStone Group Co., Ltd.
- 赵大尧 上海蔼睦医疗科技有限公司首席执行官
Zhao Dayao CEO, Shanghai AffaMed Therapeutics Co., Ltd.
- 徐敏 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
Xu Min Founder, Chairman of the Board & CEO, Pegbio. Co., Ltd.
- 张晓雷 瓴路药业(上海)有限责任公司联合创始人兼首席执行官
Zhang Xiaolei Co-Founder & CEO, Overland Pharmaceutical (Shanghai) Co., Ltd.
- 董瑞平 上海海和药物研究开发股份有限公司首席执行官
Dong Ruiping CEO, Haihe Biopharma Co., Ltd.
- 梁果 四川三叶草生物首席执行官兼执行董事
Liang Guo Chief Executive Officer and Executive Director of Clover
- 张成城 北京谷神生命健康科技有限公司董事长
Zhang Chengcheng Chairman of the Board, Beijing GuShen Life Health Science Technology Co., Ltd.
- 刘利平 深圳君圣泰生物技术有限公司创始人、首席执行官
Liu Liping Founder & CEO, HighTide Therapeutics, Inc.
- 夏国尧 上海礼邦医药科技有限公司首席执行官
Xia Guoyao CEO, Alebund Pharmaceuticals Ltd.
- 龚兆龙 思路迪(北京)医药科技有限公司董事长兼首席执行官
Gong Zhaolong Chairman of the Board & CEO, 3D Medicines Inc.
- 刘滨磊 武汉滨会生物科技股份有限公司创始人、董事长兼总经理
Liu Binlei Founder, Chairman of the Board & General Manager, Binhui Biopharmaceutical Co., Ltd.
- 贾祥波 无锡智康弘义生物科技有限公司创始人、董事长
Jia Xiangbo 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(杭州)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 Lyu 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.
黄皓宇 Huang Haoyu	信瑞诺医药(上海)有限公司首席执行官 CEO, SanReno Therapeutics (Shanghai) Co., Ltd.
薛彤彤 Xue Tongtong	苏州宜联生物医药有限公司董事长&首席执行官 Chairman & CEO MediLink Therapeutics (Suzhou) Co., Ltd.
马振坤 Ma Zhenkun	丹诺医药(苏州)有限公司创始人、总裁 Founder, CEO, TenNor Therapeutics (Suzhou) Limited
张玉冲 Zhang Yuchong	广东众生药业股份有限公司副董事长、高级副总裁 Deputy Chairman of The Board, Senior Vice-President, Guangdong Zhongsheng Pharmaceutical Co., Ltd.
周国瑛 Zhou Guoying	深圳市亦诺微医药科技有限公司董事长、首席执行官 Chairman & CEO, Immvira Co., Limited

- 陈 博
Chen Bo 康诺亚生物医药科技(成都)有限公司董事长
CEO, Keymed Biosciences (Chengdu) Limited
- 鄢和新
Yan Hexin 上海赛立维生物科技有限公司董事长兼总经理
Chairman & President, Shanghai Celliver Biotechnology Co., Ltd.
- 李国平
Li Guoping 福建广生堂药业股份有限公司董事长
Chairman, Fujian Cosunter Pharmaceutical Co., Ltd.
- 杨金夫
Yang Jinfu 南京征祥医药有限公司董事长
Chairman, Nanjing Zenshine Pharmaceuticals Co., Ltd.
- 严知愚
Yan Zhiyu 曙方(上海)医药科技有限公司联合创始人、董事长、首席执行官
Co-Founder, Chairman & Chief Executive Officer, Sperogenix (Shanghai) MedTech Co., Ltd.
- 王结义
Wang Jieyi 礼进生物医药科技(上海)有限公司董事长兼CEO
Chairman & CEO, Lyvgen Biopharma (Shanghai) Co., Ltd.
- 朱忠远
Zhu Zhongyuan 映恩生物制药(苏州)有限公司创始人及首席执行官
Founder & CEO, Duality Biologics (Suzhou) Co., Ltd.
- 卢安邦
Lu Anbang 维昇药业(上海)有限公司首席执行官
CEO, Visen pharmaceuticals (shanghai) 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.
刘 冰 Liu Bing	上海沃比医疗科技有限公司创始人、董事长 Founder, Chairman of the Board, Shanghai Wallaby Medical Therapeutics, Inc.
王 捷 Wang Jie	苏州信迈医疗器械有限公司首席执行官 CEO, SyMap Medical (Suzhou), 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
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	苏州镁伽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
姜 山 Jiang Shan	平安银行总行战略客户部总经理 General Manager of Strategic Clients Department, Ping An Bank

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| 陈鹏辉
Chen Penghui | 博远资本创始合伙人
Founding Partner, BioTrack Capital |
| 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. |
| 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创始主管合伙人
Founding Managing Partner, 3H Health Investment Management Ltd. |
| 方 敏
Fang Min | 华平投资董事总经理、中国私募股权投资联席总裁
Managing Director, Co-Head of China Private Equity, 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 |
| 孙佳林
Sun Jialin | 深圳市高特佳投资集团有限公司总经理
General Manager, ShenZhen GTJA Investment Group Co., LTD. |
| 甄 岭
Zhen Ling | ClinChoice昆翎全球董事长兼首席执行官
Global Chairman & 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. |
| 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.
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 Pharmaceutical 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
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.
张 丹 Zhang Dan	江苏谱新生物医药有限公司联席董事长 Co-Chairman, Jiangsu Hillgene Biopharma Co., Ltd.
高大鹏 Gao Dapeng	北京昭衍新药研究中心股份有限公司执行董事、总经理 Executive Director, CEO, JOINN Laboratories (China) Co., Ltd.
刘 杨 Liu Yang	北京赛赋医药研究院有限公司董事长 Chairman, SAFE Pharmaceutical Technology Company, Limited
陈建新 Chen Jianxin	上海臻格生物技术有限公司董事长兼首席执行官 CEO, Zencore Biologics 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

高明宇 Gao Mingyu	沈阳药科大学党委书记 Former Secretary of the Party Committee, Shenyang Pharmaceutical University
刘俊义 Liu Junyi	北京大学药学院原院长 Former Dean, Peking University School of Pharmaceutical Sciences
陆伟跃 Lu Weiyue	复旦大学药学院原党委书记 Former Secretary of the Party Committee, School of Pharmacy, Fudan University
刘克良 Liu Keliang	中国人民解放军军事医学科学院毒物药物研究所原所长 Former Director, Institute of Pharmacology and Toxicology Academy of Military Medical Sciences
李卓荣 Li Zhuorong	中国医学科学院北京协和医学院医药生物技术研究所原副所长 Former 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	新疆医科大学校长、中国科学院新疆理化技术研究所特聘研究员 President of Xinjiang Medical University, Distinguished Research Fellow, Xinjiang Technical Institute of Physics and Chemistry, Chinese Academy of Sciences
钱 锋 Qian Feng	清华大学药学院院长 Dean of the School, School of Pharmaceutical Sciences, Tsinghua University

重要活动

Important Events

2022 年 10 月 - 2023 年 12 月

October, 2022 - December, 2023



01

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，强党性、谋发展、做贡献，稳步推进协会各项工作高质量发展。按照发展党员工作的有关规定，我会党支部新增 2 名预备党员，截至目前，党支部共有 12 名中共党员。根据国资委党委和工经联党委的统一部署要求，党支部积极开展“学习贯彻习近平新时代中国特色社会主义思想”主题教育，全面落实中央主题教育“学思想、强党性、重实践、建新功”12 字总要求。通过理论学习、调查研究等学习实践，主题教育活动成为推动协会各项工作的重要动力。

Under the guidance of Xi Jinping Thought on the Socialism with Chinese Characteristics for a New Era, the Party branch of PhIRDA has always strengthened Party consciousness, pursued development, made contributions, and steadily promoted the high-quality development of work of PhIRDA. In accordance with relevant regulations on the admission of new Party members, the Party branch of PhIRDA added two probationary members. As of now, the Party branch of PhIRDA has a total of 12 members of the Communist Party of China (CPC). According to the overall plan and direction of the CPC Committee of the State-owned Assets Supervision and Administration Commission of the State Council and the CPC Committee of the China Federation of Industrial Economics, the Party branch of PhIRDA actively carried out the theoretical study program on “Studying and Implementing Xi Jinping Thought on Socialism with Chinese Characteristics for a New Era,” fully implementing the overall requirement of “Learning thoughts, strengthening Party spirit, emphasizing practice, and making new contributions.” Through activities such as theoretical learning, investigation and research, the theoretical study program becomes a crucial driving force for various work of PhIRDA.



学习习近平总书记在河北考察并主持召开深入推进京津冀协同发展座谈会时的重要讲话精神
Studying the speech of General-Secretary Xi Jinping at the meeting on promoting the coordinated development of the Beijing-Tianjin-Hebei Region during his inspection tour in Hebei province



主题教育读书班
Reading Activity of Theoretical Study Program



中国药促会党支部全体党员奋发向上，积极作为，充分发挥党支部战斗堡垒作用和党员先锋模范作用。在上级党委开展的“两优一先”评选表彰工作中，我会党支部被授予“先进基层党组织”称号，党支部书记冯岚同志被授予“优秀共产党员”称号。

The Party branch of PhIRDA fully plays a key role and all members play their exemplary roles by working diligently and forging ahead. In awarding the outstanding Party members, exemplary Party workers, and advanced community-level Party organizations by the CPC Committee of the China Federation of Industrial Economics, the Party branch of PhIRDA was honored as “Advanced community-level Party Organization”, and Ms. Feng Lan, Party branch Secretary was honored as “Outstanding Party Member”.

02 重点工作会议 >> Important Meetings

2023 年会长会议扩大会议（2023 年 10 月 15 日 · 深圳）
2023 PhIRDA President Board Meeting (October 15, 2023 • Shenzhen)

我会 2022-2023 年度会长李佳，副会长陈启宇、丁列明、刘殿波、吴晓滨，秘书长冯岚，监事舒畅参加会议。会议总结了十一届理事会四次会议以来的重要成果，并对下一阶段重点工作进行介绍。我会创新医疗器械专委会主委王广志、香港生物医药创新协会会长卢毓琳以及部分副会长单位及会员单位代表受邀出席会议。

PhIRDA 2022-2023 Annual Chairman Li Jia, Vice Presidents Chen Qiyu, Ding Lieming, Liu Dianbo, Wu Xiaobin, Secretary-General Feng Lan, and Supervisor Shu Chang attended the meeting. The meeting summarized the results of the work priorities since the Fourth Meeting of the 11th Board of Directors and identified priorities for the next stage. Wang Guangzhi, Chairman of PhIRDA Innovative Medical Devices Specialty Committee, Yuk Lam LO, President of HK Bio-Med Innotech Association, and representatives of Vice-President members were invited to attend the meeting.



会议现场
Plenary Meeting



参会代表合影
Group Photo of Representatives

03

>> 立足新阶段，打造高水平对话平台 Ground Efforts in the New Stage, Build a High-level Dialogue Platform

2022 第七届中国医药创新与投资大会（2023年3月29-31日·苏州）
The 7th China BioMed Innovation and Investment Conference (March 29-31, 2023 • Suzhou)

由中国药促会、香港交易所、艾美达咨询、鼎新研究中心共同主办的第七届中国医药创新与投资大会在苏州工业园区召开。

本届大会特设 7 个路演专场、12 个主题论坛和若干卫星会和活动；首设近万平米“临床研究和药械创新”专题展区，众多顶级临床研究机构、创新研发企业、地方生物医药产业园区、知名证券机构、政府部门等主体重磅亮相展区，全方位、多角度展示临床诊疗、创新研发、成果转化等诸多方向的能力；增设人才交流专区，定向邀请国内诸多医药高等学府，为各产业主体提供精准、高端的人才资源储备与输送渠道。

The 7th China BioMed Innovation and Investment Conference (CBIIC), co-hosted by PhIRDA, Hong Kong Exchanges and Clearing Limited (HKEX), iMeta, and Ding Xin Pharmaceutical Innovation Research Center, was successfully held in Suzhou Industrial Park.

The 7th CBIIC set 7 parallel sessions for roadshows, 12 forums, and various satellite meetings and activities. The exhibition themed “Clinical Research and Medical Device Innovation” was launched for the first time, covering nearly 10,000 m². This exhibition brought numerous top-tier clinical research institutions, innovative R&D companies, local pharmaceutical industrial parks, well-known securities institutions, government departments, and other key stakeholders together. It demonstrated capabilities in clinical diagnosis and treatment, innovative R&D, and the transformation of achievements in a comprehensive and multi-dimensional manner. In addition, a talent exchange zone was added, and many domestic pharmaceutical universities were invited to provide a targeted and high-end talent pool and pipeline for the industry.



毕井泉 全国政协常委、经济委员会副主任，
中国国际经济交流中心常务副理事长
Bi Jingquan, Member of the Standing Committee, Vice-
Chairman of the Committee on Economic Affairs of the CPPCC
National Committee, Executive Vice Chairman of CCIEE



徐景和 国家药监局党组成员、副局长
Xu Jinghe, Member of NMPA Leading Party Member's
Group and NMPA Deputy Commissioner



吴庆文 苏州市市长
Wu Qingwen, Mayor of Suzhou Municipal People's Government



蒋建东 中国工程院院士、中国药促会 2017-2018 年度会长、中国医学科学院药物研究院院长
Jiang Jiandong, Academician of the Chinese Academy of Engineering, 2017-2018 Annual Chairman of PhIRDA, President of Institute of Pharmaceutical Sciences, Institute of Materia Medica, Chinese Academy of Medical Sciences & Peking Union Medical College



李佳 中国药促会 2022-2023 年度会长、中国科学院上海药物研究所所长
Li Jia, 2022-2023 Annual Chairman of PhIRDA, Director of Shanghai Institute of Materia Medica, Chinese Academy of Sciences



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



李燕 中国药促会副会长、齐鲁制药集团总裁
Li Yan, Vice President of PhIRDA, President of Qilu Pharmaceutical Group



杨晓明 中国医药集团总工程师、首席科学家
Yang Xiaoming, Chief Engineer and Chief Scientist of SINOPHARM



欧冠升 香港交易所集团行政总裁
Nicolas Aguzin, CEO of Hong Kong Exchanges and Clearing Limited



梁红 华泰证券机构业务委员会主席
Liang Hong, Chairman of Institutional Business Committee of Huatai Securities



开幕式现场
Opening Ceremony



大会展区
Exhibition Area

溶瘤病毒创新药研究高峰论坛（2023年4月8日·北京） Oncolytic Virus Drugs Clinical R&D Forum (April 8, 2023 • Beijing)

2023年4月8日，由我会主办、武汉滨会生物科技股份有限公司协办的“溶瘤病毒创新药研究高峰论坛”在北京召开。来自溶瘤领域的专家、研究者、企业家、研发企业代表、服务机构从业者及媒体代表共聚一堂，论道溶瘤病毒创新药研究，推动临床研究与成果转化。

On April 8, 2023, the Oncolytic Virus Drugs Clinical R&D Forum, hosted by PhIRDA and co-organized by Wuhan Binhui Biotechnology Co., Ltd., was held in Beijing. Experts, scholars, entrepreneurs, representatives from R&D companies, service organizations, and media in the oncolytic field gathered together to discuss the research of innovative oncolytic virus drugs, promoting clinical research and the transformation of research achievements.



程书钧 中国工程院院士、国家癌症中心 / 中国医学科学院肿瘤医院研究员

Cheng Shujun, Academician of Chinese Academy of Engineering, Researcher of National Cancer Center of China & Cancer Hospital of Chinese Academy of Medical Sciences



会议现场
Plenary Meeting



主题讨论：创新与合作——推动溶瘤病毒药物研发
Panel: Innovation and Cooperation for Better R&D of
Oncolytic Virus Drugs

第八届中国医药创新与投资大会（2023年9月25-27日·苏州）

The 8th China BioMed Innovation and Investment Conference (CBIIC) (September 25-27, 2023 • Suzhou)

由中国国际经济交流中心指导，我会联合香港交易所、中国农工民主党中央健康中国建设工作委员会、艾美达咨询、鼎新研究中心共同主办的“第八届中国医药创新与投资大会”在苏州工业园区召开。

本届大会聚焦源头创新活力，探讨我国医药产业在当前国际形势下的资本融合创新。共设置6个路演专场、8场专业论坛，来自国内外投资机构、医药创新企业及研究院所等百余家机构和政府领导、业界领袖、专家学者、知名企业家、投资机构负责人及媒体齐聚一堂，共享生物医药行业盛宴。



何维 全国人大常委会副委员长、中国农工民主党主席

He Wei, Vice-Chairman of the Standing Committee of the National People's Congress,
Chairman of the Central Committee of Chinese Peasants and Workers Democratic Party



于旭波 中国通用技术（集团）控股有限责任公司
董事长、党组书记

Yu Xubo, Chairman & Secretary of Party Leadership Group,
China General Technology (Group) Holding Co., Ltd.



王忠民 深圳市金融稳定发展研究院理事长、
全国社会保障基金理事会原副理事长

Wang Zhongmin, Chairman of Shenzhen Financial Stability
& Development Institute, Former Vice-Chairman of the
National Council for Social Security Fund

Under the guidance of the China Center for International Economic Exchanges, the 8th China BioMed Innovation and Investment Conference (CBIIC), co-hosted by PhIRDA, Hong Kong Exchanges and Clearing Limited (HKEX), the Healthy China Initiative Working Committee of the Central Committee of the Chinese Peasants and Workers Democratic Party, iMeta, and Ding Xin Pharmaceutical Innovation Research Center, was held in Suzhou Industrial Park.

The 8th CBIIC focused on the vitality of innovation at the source, discussing capital empowering innovation of China's pharmaceutical industry under current international circumstances. The 8th CBIIC set 6 parallel sessions of roadshows and 8 forums, attracting senior officials, leaders of pharmaceutical industry, experts, scholars, renowned entrepreneurs, and journalists from over 100 investment institutions, pharmaceutical innovative companies, and research institutions in China and abroad, providing a knowledge feast for the audience.



吴庆文 苏州市市长
Wu Qingwen, Mayor of Suzhou Municipal
People's Government



孙磊 国家药品监督管理局
医疗器械技术审评中心主任、党委副书记
Sun Lei, Director-General and Deputy Party Secretary of
Center for Medical Device Evaluation, NMPA



李佳 中国药促会 2022-2023 年度会长、
中国科学院上海药物研究所所长
Li Jia, 2022-2023 Annual Chairman of PhIRDA,
Director of Shanghai Institute of Materia Medi-
ca, Chinese Academy of Sciences



冯岚 中国药促会秘书长
Feng Lan, Secretary-General of PhIRDA



陈翊庭 香港交易所联席营运总监
Bonnie Y Chan, Co-Chief Operating
Officer of HKEX



大会现场
The Conference



(从左至右：宋瑞霖执行会长、丁健院士、王磊先生、吴晓滨博士、任晋生董事长)
Song Ruilin, Ding Jian, Leon Wang, Wu Xiaobin, Ren Jinsheng (From Left to Right)



(从左至右：陈力博士、陈翊庭女士、田源博士、丁列明董事长、李茜女士)
Chen Li, Bonnie Y Chan, Tian Yuan, Ding Lieming, Li Qian (From Left to Right)

大会期间举办的以“粤港澳大湾区药械监管协同与创新发展”为主题的医药政策分享论坛备受瞩目。论坛邀请到了中国食品药品国际交流中心主任董江萍、广东省药品监督管理局副局长王玲、澳门特别行政区药物监督管理局副局长李世恩、香港特别行政区卫生署药物办公室总药剂师林丰盛等主要领导出席，且大家围绕药械监管创新与产业统筹发展为主线分别作了主题报告。这也是粤港澳地区监管部门首次相聚在大湾区之外，深入内地，与国家药品监管机构共同探讨和分享监管经验和未来合作展望。

During the Conference, the Pharmaceutical Policy Sharing Forum under the theme of “Coordinated and Innovative Development of Drug and Medical Devices Regulation in the Greater Bay Area” attracted significant attention. At the forum, Dong Jiangping, Director-General, China Center for Food and Drug International Exchange, Wang Ling, Deputy Director-General, Guangdong Medical Products Administration, Lei Sai Ian, Deputy Director, Pharmaceutical Administration Bureau, Macao SAR, and LAM Fung Shing, Chief Pharmacist, Drug Office, Department of Health, Hong Kong Special Administrative Region addressed keynote speeches focusing on the topic of the regulation development of medical devices and coordinated industrial development. This is the first time that departments of regulation from Guangdong, Hong Kong and Macao gathered in the region beyond the Greater Bay Area, to share regulation experience and discuss future prospects of cooperation with NMPA.



与会领导合影
Group Photo of Guests

(从左至右：林丰盛总药剂师、李世恩副局长、董江萍主任、宋瑞霖执行会长、王玲副局长、杨义辉先生)
LAM Fung Shing, Lei Sai Ian, Dong Jiangping, Song Ruilin, Wang Ling, YEUNG Yee Fai (From Left to Right)

第二届上海合作组织医药合作发展大会（2023年9月25日·苏州）

The 2nd Shanghai Cooperation Organization Pharmaceutical Cooperation Development Conference (September 25, 2023 • Suzhou)

2023年9月25日，由我会、上海合作组织睦邻友好合作委员会、上海合作组织秘书处和哈萨克斯坦共和国驻华大使馆共同主办的“第二届上海合作组织医药合作发展大会”在苏州召开。本次大会是上合组织相关国家第二次在上合组织框架下举办的医药领域政府间的高级别代表参与的盛会，既是展示中国生物医药创新实力的一次重要契机，也是推进“一带一路”健康丝绸之路建设的重要举措。

与会各国共同发布了《苏州倡议》，为构建更加紧密的上合组织命运共同体注入新的强劲动力。

The 2nd Shanghai Cooperation Organization Pharmaceutical Cooperation Development Conference, co-hosted by PhIRDA, Good-Neighborliness, Friendship and Cooperation Commission of the Shanghai Cooperation Organization (GNFCC SCO), Secretariat of the Shanghai Cooperation Organization, and Embassy of the Republic of Kazakhstan in the People's Republic of China, was successfully held in Suzhou on September 25, 2023. The Conference is a brand event under the SCO framework held for the second time, bringing together the senior officials from the governments of the SCO countries. The Conference is an important opportunity to present China's pharmaceutical innovation capacity and a significant measure to promote the building of a Health Silk Road.

The participating countries jointly announced the *Shanghai Cooperation Organization Pharmaceutical Cooperation Development Conference Suzhou Initiative*, injecting new and strong vitality to building a closer SCO community with a shared future.





“加强国际医药产业合作，推动上合组织框架下药品监管互认”主题讨论
Panel: Strengthen International Cooperation in the Pharmaceutical Industry, Promote Mutual Recognition of Drug Regulation under the SCO Framework

(从左至右：宋瑞霖执行会长、吉尔吉斯斯坦卫生部国企吉尔吉斯药业沙基罗娃·古莉米拉总经理、乌兹别克斯坦先进技术中心季尔巴尔·达利莫娃副主任、丁列明董事长、刘殿波总裁、陈力博士、阿斯利康陈冰先生)
Song Ruilin, Shakirova Gulmira Abidinovna, Dilbar Dalimova, Ding Lieming, Liu Dianbo, Chen Li, Chen Bing (From Left to Right)



参会嘉宾合影
Group Photo of Guests



崔丽
上海合作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 Commission (GNFCC) of the
Shanghai Cooperation Organization



尼亚扎利耶夫·努兰·萨德罗维奇
上海合作组织副秘书长
Niyazaliev Nuran, Deputy Secretary-General of the Shanghai
Cooperation Organization



赛义德·海达尔·穆罕默迪
伊朗食品药品监督管理局局长
Seyyed Heydar Mohammadi,
Head of Iran Food and Drug Administration



阿西姆·劳夫
巴基斯坦药监局局长
Asim Rauf, Chief Executive Officer of Drug Regulatory
Authority of Pakistan



图尔迪库洛娃·莎赫洛·乌特库罗夫娜
乌兹别克斯坦高等教育、科学与创新部副部长
Shahlo Turdikulova, Deputy Minister of Ministry of Higher
Education, Science and Innovation of the Republic of
Uzbekistan



亨邦杰
柬埔寨卫生部国务秘书
Heng Bunkiet, Secretary of State, Ministry of Health of the
Kingdom of Cambodia

2023中国国际生物医药大会（2023年11月17-18日·海南）
2023 China International Biopharma Conference (November 17-18, 2023 · Hainan)

由中国医药创新促进会、海南广播电视总台（集团）联合主办的“2023 中国国际生物医药大会”在海南国际会展中心成功举办。

政府相关部门领导、两院院士、专家学者、药企高管、国内外医疗机构管理者、相关投融资机构等多位嘉宾出席，围绕国家政策、制度创新、前沿技术等话题展开深入交流。

The 2023 China International Biopharma Conference, co-hosted by PhIRDA and Hainan Broadcasting Station (Group), was successfully held in Hainan International Convention and Exhibition Center.

Government officials, academicians of Chinese Academy of Engineering and Chinese Academy of Sciences, experts and scholars, executives from pharmaceutical companies, senior representatives of domestic and international medical institutions, representatives from relevant investment and financing institutions, and other distinguished guests attended and had in-depth discussions revolving around national policies, institutional innovation, and cutting-edge technologies.



大会启动仪式
Launching Ceremony of the Conference



① 蒋建东 中国工程院院士、中国医学科学院药物研究院院长
Jiang Jiandong, Academician of Chinese Academy of Engineering, President, Institute of Materia Medica, Chinese Academy of Medical Sciences & Peking Union Medical College

② 宋瑞霖 中国医药创新促进会执行会长
Song Ruilin, Executive President of PhIRDA

③ 刘立武 海南省工业和信息化厅党组书记、厅长
Liu Liwu, Secretary of the Party Leadership Group and Head of the Department of Industry and Information Technology of Hainan Province

④ 郭志民 海南广播电视总台（集团）党组书记、台长
Guo Zhimin, Secretary of the Party Leadership Group and President of Hainan Broadcasting Station (Group)

⑤ 吴一龙 广东省人民医院首席专家
Wu Yilong, Chief Expert of Guangdong Provincial People's Hospital

2023首届浦江生物医药源头创新论坛（2023年12月2日·上海）

The 1st Pujiang Pharmaceutical Original Innovation Forum (December 2, 2023 • Shanghai)

2023年12月2日，由我会主办，上海市科学技术委员会、上海市经济和信息化委员会、上海市卫生健康委员会支持，上海生物医药行业协会和上海复星医药（集团）股份有限公司承办的“2023首届浦江生物医药源头创新论坛”在上海举办。论坛以“激活源头创新‘第一公里’”为主题，邀请国内外顶尖高校科研院所的院士和科学家、临床研究领军专家，政策制定者、头部风险投资机构合伙人以及创新企业领袖等政、产、学、研、医、资界200多位代表齐聚一堂，围绕生物医药的原研转化、创新路径和政策机制展开深入交流，旨在推动我国生物医药产业高质量、现代化发展。

On December 2, 2023, “The First Pujiang Biopharmaceutical Original Innovation Forum”, hosted by PhIRDA, supported by Science and Technology Commission of Shanghai Municipality, Shanghai Municipal Commission of Economy and Informatization, and Shanghai Municipal Health Commission, and organized by the Shanghai Biopharmaceutics Industry Association and Shanghai Fosun Pharmaceutical (Group) Co., Ltd., was held in Shanghai. Themed with “Stimulate the ‘First Mile’ of Original Innovation”, the forum has attracted more than 200 representatives from the industrial, academic, research, clinical, and financial circles, including academicians, scientists from top research institutions in China and abroad, leading experts in clinical research, decision-makers, partners from prominent venture capital firms, and leaders of innovative companies gathered to engage in profound discussions. With the focus of the discussions on transformation of innovative research, innovative pathways, and policy mechanisms in the pharmaceutical industry, the forum aimed to promote the high-quality and modern development of China’s pharmaceutical industry.

嘉宾集锦 Distinguished Guests



陈竺 中国红十字会会长、上海交通大学医学院附属瑞金医院终身教授、中国科学院院士

Chen Zhu, President of Red Cross Society of China, Tenured Professor of Ruijin Hospital of Shanghai Jiaotong University School of Medicine, Academician of Chinese Academy of Sciences



毕井泉 全国政协常委、经济委员会副主任、中国国际经济交流中心常务副理事长

Bi Jingquan, Member of the Standing Committee, Vice-Chairman of the Committee on Economic Affairs of the CPPCC National Committee, Executive Vice Chairman of CCIEE



寿子琪 全国政协常委、全国工商联副主席、上海市政协副主席、上海市工商联主席
Shou Ziqi, Member of the Standing Committee of the CPPCC National Committee, Vice Chairman of All-China Federation of Industry and Commerce, Vice Chairman of the CPPCC Shanghai Committee, Chairman of Shanghai Federation of Industry and Commerce



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



鲁白 清华大学药学院终身教授
Lu Bai, Tenured Professor, School of Pharmaceutical Sciences, Tsinghua University



郭广昌 复星国际董事长
Guo Guangchang, Chairman of Fosun International



陈启宇 中国医药创新促进会副会长、复星国际执行董事兼联席首席执行官
Chen Qiyu, Vice President of PhIRDA, Executive Director & Co-CEO, Fosun International

04

贯彻新理念，发挥高端智库作用

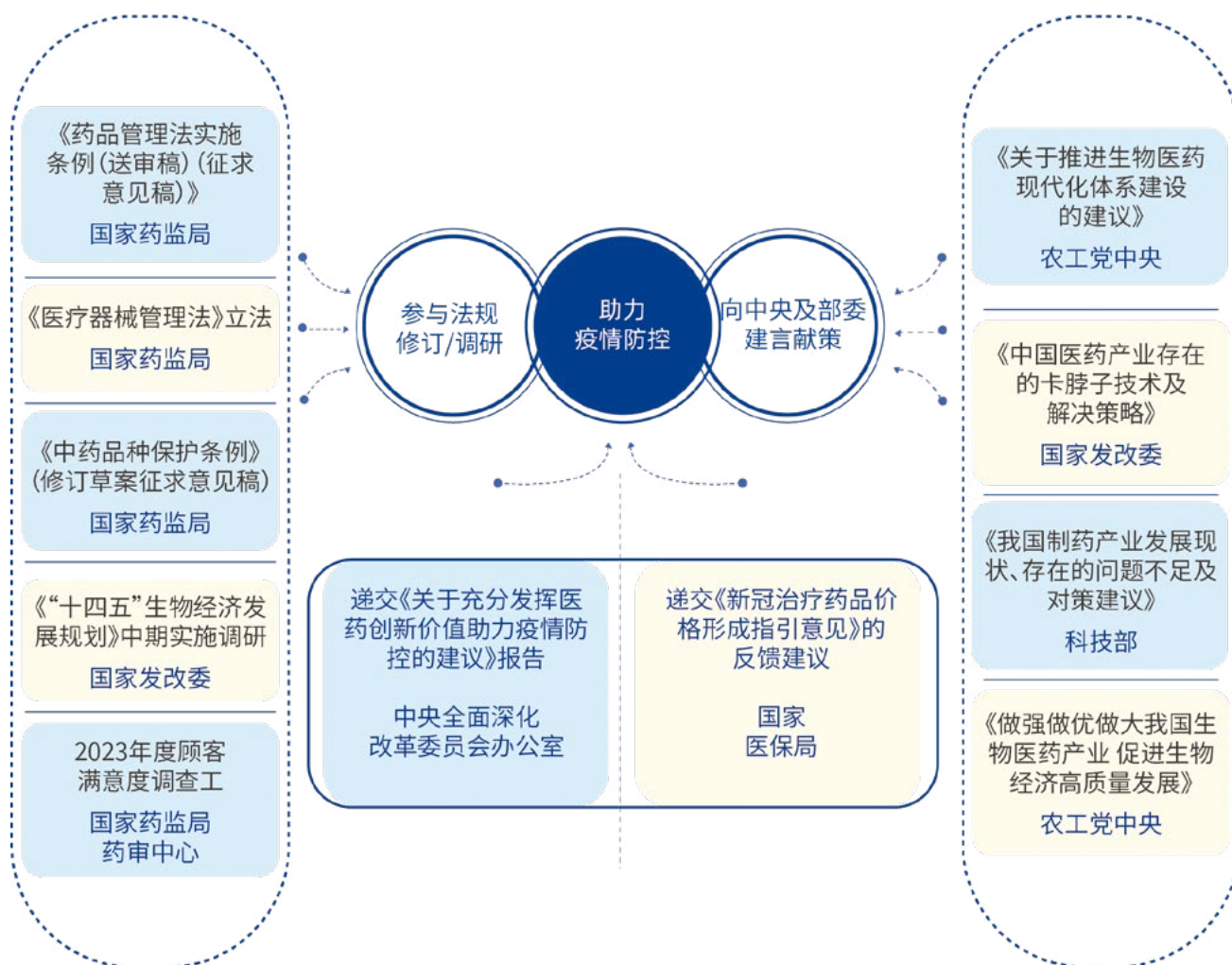
>> Implement New Concepts, Leverage the Role as a High-end Think Tank

向政府有关部门建言献策

Actively Submit Advice and Suggestions to Government Departments

我会受中央多个部委委托，持续发挥高端智库作用，开展医药政策与战略专题研究，为我国完善医药政策和产业发展建言献策，智库品牌影响力与日俱增。

Entrusted by departments of several ministries, PhIRDA continues to play the role of a high-end think tank, and conducted research on pharmaceutical policies and strategies, providing valuable advice on the improvement of pharmaceutical policies and the development of the industry in China. PhIRDA's influence as a high-end think tank is expanding steadily.



开展多项研究课题，推动政策体系完善和医药创新环境改善

Conduct Several Projects, Facilitate Better Policy Systems and Pharmaceutical Innovation Environment

洞察产业共性问题，以期推动制度加速落地，我会政策研究中心自主开展的课题研究有：创新药医保准入与创新支付研究、建立中国特色的创新药支付保障体系研究、药品上市许可持有人制度研究、中国创新器械审评制度改革、中国创新药出海技术路径研究等。

With insights into the common issues in the industry and the aim of expediting the implementation of systems, the Policy Research Center of PhIRDA independently conducted the following projects: Research on Medical Insurance Access and Innovative Payment for Innovative Drugs, Research on the Establishment of Innovative Drugs Payment Security System with Chinese Characteristics, Research on Marketing Authorization Holder, Reform of Review and Approval of Innovative Medical Devices in China, and Pathways for the Going Global of China's Innovative Drugs.



受科技部重大专项司委托，高质量完成“中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”研究项目，全面了解我国创新药物研发新兴技术的发展态势，形成报告上报科技部。

Entrusted by the Department of Major Science and Technology Project of Ministry of Science and Technology (MoST), PhIRDA completed *“A Comparative Study of R&D and Transformation Capability of Innovative Drugs in China and Abroad and Frontiers”* with high quality, comprehensively delving into the emerging trends in the innovative drug R&D, drafted the report and submitted to the Ministry of Science and Technology.

受北京市卫健委委托，开展“北京市首批研究型病房动态评估”，针对 10 家医院通过现场实地调研、召开座谈会，深入分析研究型医院对医药产业建设的实际影响，提出联动研究型医院和产业，从源头提高产业创新性、打造国际医药科技创新中心的政策建议；积极打造临床研究机构和创新医药产业的共建平台，从源头推进产学研医高度结合。

Entrusted by Beijing Municipal Health Commission, PhIRDA conducted the “**Dynamic Assessment of the First Demonstration Units for Research-oriented Ward Construction in Beijing**”. Through on-site investigation and symposiums with 10 hospitals, PhIRDA deeply analyzed the impact of research-oriented hospitals on pharmaceutical industry. PhIRDA proposed to enhance industry innovation from the source and establish a collaborative relationship between research-oriented hospitals and the industry. To be specific, clinical research institutions and the innovative pharmaceutical industry jointly establish a platform, promoting a highly integrated industry-academia-research-healthcare approach from the source.

北京市
卫健委课题



北京大学肿瘤医院



北京协和医院



天坛医院



北京大学第一医院



医科院肿瘤医院



北京宣武医院

参与重要政策法规研讨与修订工作，推动政策体系完善和医药创新环境改善

Participate in Discussion and Amendments of Important Policies and Laws and Regulations, Facilitate the Improvement of Policy System and Pharmaceutical Innovation Environment

关注行业迫切需求，推动立法与规章制度完善，如针对《科技伦理审查办法》《关于加强对委托生产药品上市许可持有人监管工作的通知》等法规文件，广泛听取产业声音并及时反馈相关部门。

建立政企沟通平台，拓宽政企合作助力产业发展，组织会员单位参加 CDE 有关课题及系列研讨会。

Focus on the urgent needs in industry, promote the improvement of legislation and regulations.

For example, PhIRDA listened to the comments and suggestions from the industry about regulatory documents including *Measures for Scientific and Technological Ethics Review* and *Notice on Strengthening Supervision on the Contract Manufacturing of the Drug Marketing Authorization Holder* and submitted advice to related government departments.

Establish a platform for exchanges between the government and industry, expand collaboration to facilitate industrial development. PhIRDA organized members to participate in the project seminar held by the CDE.



企业座谈研讨会（2023 年 4 月 14 日 无锡）
Enterprise Symposium (April 14, 2023, Wuxi)



以患者为核心的罕见疾病药物研发研讨会（2023 年 2 月 28 日 北京）
Seminar on Patient-Centered Drug R&D for Rare Diseases (February 28, 2023, Beijing)

持续关注行业热点、共性问题，通过组织召开座谈会、发表学术文章、出版研究报告等，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。

PhIRDA consistently followed industrial trends and common issues by organizing symposiums, publishing academic articles and research reports, provided a science-based and valuable reference for policy formulation, contributing to the development of a better pharmaceutical innovation ecology.

积极拓宽发声渠道扩大影响力 Expanding Channels for Voicing, Enlarging Influence



《改革内参》收录
《中国医药创新面临的挑
战及其应对》
*Challenges to China's
Pharmaceutical Innovation
and Its Response* was
published on the *Reform
Internal Reference*

《世界临床药物》发表
《中国临床试验数据监管
改革的分析与思考》
*Analysis and Thinking on the
Reform of Clinical Trial Data
Supervision in China* was
published on the *World Clinical
Drug*

《中国医药报》发表
《2022 年我国罕见疾病药
品获批情况盘点》
*Review of the Approved Drugs
for Rare Diseases in 2022 in
China* was published on the
China Pharmaceutical News

医药政策研究专栏

在药促会微信公众号定期发布原创文章

PhIRDA regularly published original articles on official WeChat account

政策研究中心原创专栏

- > FDA加速审评再出招:分步实时申请审评试点计划 >>
- > “以患者为中心”引领药物研发新方向:全球进展与趋势展望 >>
- > 加快完善我国药品技术指导原则体系,产业相关方应主动发挥力量 >>
- > 产业调研: ICH五年成绩单,开启新年新征程 >>
- > 进口仿制双轮驱动 多维协同回应急需——盘点2022年我国罕见病药物加速获批上市情况 >>
- > 创新药审评再加速,开启政策升级新篇章 >>
- > 中国临床试验数据监管改革的分析与思考 >>
- > 创新医疗器械改革系列-行业思考 | 医疗器械高质量发展,政策端改革如何发力? >>
- > 创新药出海专题系列FDA推动药品监管国际化进展及启示 >>
- > 研发面向临床需求的新药,堵点在哪里?——2022年《药品审评报告》与《新药临床试验年报》分析 >>
- > 附条件批准政策升级蓄力,加强上市后监管夯实管理闭环 >>
- > 最严最细的委托生产文件出台后,医药产业的变化和政策方向 >>
- > 医保支付改革助力创新药产业高质量发展的思考 >>
- > 从资本寒冬到国产创新药放弃“国谈”——完善医保支付视角之思考 >>
- > 医保目录制定为何两难?——由委托代理关系引发的思考 >>
- > 构建创新药支付保障体系的初步展望 >>
- > 创新支付专题系列 | 美国卫生部公布处方药降价最新试点方案 >>
- > 创新支付专题系列 | 从医保目录“遗漏”品种挖掘高临床价值新药的可及性 >>
- > 创新支付专题系列 | 从体系建立视角对完善创新药支付保障的思考 >>
- > 从中美Biotech商业化模型差异浅析我国医药行业发展 >>
- > 关于罕见病目录定位与提升药物创新性、可及性的探讨 >>
- > “三医协同视角”探索创新药入院困境的破解之路 >>
- > 2022年我国医药科技政策概览:全面发力科技成果转化 >>
- > 从罗氏声明探讨药品知识产权保护相关问题 >>
- > 药品知识产权保护的地域性问题剖析 >>

05

构建新格局，推进高质量对外交流

>> Establish a New Paradigm, Promote High-quality International Collaboration

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。截至当前，我会已向IFPMA 25 个ICH 工作组推荐50 名专家（包括14 名组长，12 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%。已有107 位我会推荐的专家被纳入35 个CDE ICH 专家工作组。

ICH 在加拿大温哥华举行工作组会议，我会7 位专家通过线上和线下形式参加，参与各议题内容讨论与协调工作（2023 年6 月9-14 日）。

PhIRDA actively organized experts to engage in work aligning China's research and formulation of drug regulatory standards and policies in line with international standards, facilitating the transformation and implementation of ICH Guidelines. Up to now, PhIRDA has recommended 50 experts (including 14 Lead and 12 Alternate) to 25 IFPMA ICH Task Forces, accounting for more than 53% of the total number of IFPMA experts worldwide. A total of 107 experts recommended by PhIRDA have engaged in 35 CDE ICH Working Groups.



The ICH Assembly meeting was held in Vancouver, Canada. Seven IFPMA ICH experts recommended by PhIRDA participated in the meeting in-person or virtually, engaging in guideline's discussion and harmonisation (June 9-14, 2023).



ICH 大会在捷克布拉格举行。5 位我会推荐的IFPMA ICH 专家现场参加了相关指导原则工作组会议（2023 年10月28 日-11 月1 日）。

The ICH Assembly meeting was held in Prague, Czech Republic. 5 IFPMA ICH experts recommended by PhIRDA attended in person and participated in the meetings of related ICH Task Forces. (October 28-November 1, 2023).



合影
Group Photo of ICH Assembly Meeting



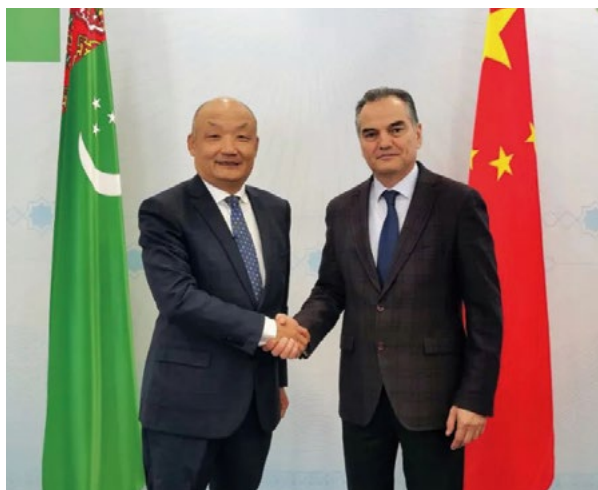
会议现场
Meeting

持续推进境内外交流合作

Steadily Promote International Exchanges and Cooperation

宋瑞霖执行会长拜访土库曼斯坦驻华特命全权大使巴拉哈特·杜尔德耶夫（2022年10月12日·北京）。

Executive President Song Ruilin met with Parakhat Durdyev, Ambassador Extraordinary and Plenipotentiary of Turkmenistan to the People's Republic of China (October 12, 2022 • Beijing).



我会执行会长宋瑞霖和亚太医药交流中心主任孙君泓代表双方签署合作备忘录（2023年2月17日·悉尼）。

On behalf of PhIRDA and Asia-Pacific Bio-Med Exchange Centre INC (APBMEC), Song Ruilin, Executive President of PhIRDA and Sun Junhong, Director of APBMEC, signed a Memorandum of Cooperation (February 17, 2023 • Sydney).



中国药促会代表团访问香港（2023年2月27-28日·香港）

PhIRDA Delegation Visited Hong Kong (February 27-28, 2023 • Hong Kong)



我会与香港科技大学签署合作备忘录

PhIRDA and the Hong Kong University of Science and Technology (HKUST) signed a Memorandum of Understanding (MoU)

2023年2月27-28日，受中国香港特区政府相关机构邀请，我会组织22家会员单位访问香港科技大学、香港科技园、香港特区政府投资推广署、引进重点企业办公室，与特首政策组组长黄元山博士，财经事务及库务局局长许正宇，香港科技大学校长、中国科学院院士叶玉如进行会谈，并与香港科技大学签订合作备忘录，共同建立“大湾区生物医药国际创新中心”和“大湾区生物医药发展政策研究中心”。

Upon the invitation from HKSAR Government and related institutions, PhIRDA organized a delegation composed of senior representatives from 22 members, visited the Hong Kong University of Science and Technology, Hong Kong Science & Technology Parks (HKSTP), Invest Hong Kong (InvestHK), and Office for Attracting Strategic Enterprises (OASES) on February 27-28, 2023. PhIRDA Delegation met with Dr. Wong Yuen Shan, Head of the Chief Executive's Policy Unit, Christopher Hui, Secretary for Financial Services and the Treasury Bureau, and Nancy Yuk-Yu, President of the Hong Kong University of Science and Technology (HKUST), Academician of the Chinese Academy of Sciences (CAS) and signed a Memorandum of Understanding (MoU) with HKUST, to jointly establish the “Greater Bay Area Center for International BioMed Innovation” and “Greater Bay Area Center for Policy Research on BioMed Development”.



座谈会
Plenary Meeting



全体合影
Group Photo

中国药促会代表团访问新加坡（2023年3月2日·新加坡）

PhIRDA Delegation Visited Singapore (March 2, 2023 • Singapore)

我会年度会长李佳和执行会长宋瑞霖会见新加坡通商中国主席、前贸工部部长兼国家发展部高级政务部长李奕贤。

受新加坡经济发展局邀请，我会组织20家会员单位访问新加坡科技研究局、新加坡经济发展局及新加坡证券交易所等机构。

PhIRDA 2022-2023 Annual Chairman Li Jia and Executive President Song Ruilin met with Lee Yi Shyan, Chairman of Business China and Former Minister of the Ministry of Trade and Industry and Senior Minister of State Ministry of National Development in Singapore.

Upon the invitation from Singapore Economic Development Board (EDB), PhIRDA organized 20 members to visit institutions including the Agency for Science, Technology and Research (A*STAR), EDB, and Singapore Exchange (SGX).



双方合影 Group Photo
(从左至右：宋瑞霖执行会长、李佳会长、
李奕贤主席、博彦科技王斌董事长)

Song Ruilin, Li Jia, Lee Yi Shyan, Wang Bin (From Left to Right)



会谈现场
Plenary Meeting



参会代表合影
Group Photo of Representatives

欧洲制药工业协会联合会（EFPIA）代表团一行拜访我会（2023年9月11日·北京）。

European Federation of Pharmaceutical Industries and Associations (EFPIA) Delegation visited PhIRDA (September 11, 2023 • Beijing).



组织上合组织相关国家医药卫生代表及驻华使领馆代表、重要外宾参观苏州生物医药产业园（BioBAY）及园区创新药企业（2023年9月26日·苏州）。

PhIRDA organized senior representatives from pharmaceutical departments and embassies of the SCO countries to visit BioBAY and innovative pharmaceutical enterprises in Suzhou (September 26, 2023 • Suzhou).



2023年10月30日，中国药促会执行会长宋瑞霖会见国际医药企业联盟协会（INTERPAT）中国及大中华区主席John Conway一行（2023年10月30日·北京）。
Song Ruilin, Executive President of PhIRDA met with John Conway, Chair of Interpat China & Greater Asia WG and Interpat Delegation (October 30, 2023 • Beijing).



中国药促会代表团访问日本（2023年11月28-30日·东京） PhIRDA Delegation Visited Japan (November 28-30, 2023 • Tokyo)

受日本制药工业协会（JPMA）及武田制药邀请，我会执行会长宋瑞霖率代表团一行赴日本考察交流，拜访日本制药工业协会，共同开展中日医药产业项目对接交流活动；并实地考察武田制药、日本国立癌症研究中心及日本湘南健康创新园。

Upon the invitation from Japan Pharmaceutical Manufacturers Association (JPMA) and Takeda Pharmaceutical Co., Ltd., led by Executive President Song Ruilin, PhIRDA Delegation visited Japan and conducted various exchanges in Tokyo, Japan. PhIRDA and JPMA jointly host the SINO-Japan Pharmaceutical Industrial Meeting. PhIRDA Delegation has also visited Takeda, National Cancer Center Japan, and Shonan Health Innovation Park (Shonan iPark).



合影
Group Photo

06

凝聚专家力量，发挥专业委员会智库作用

>> Pool the Strength of Experts, Leverage the Role of Specialty Committees as Think Tanks

不断丰富和完善专业委员会设置

Continuously Improve the Structure of Specialty Committees

自2022年11月以来，我会新成立2个专业委员会，并完成11个专委会换届工作。

Since November 2022, PhIRDA has established two specialty committees and conducted the general elections of 11 specialty committees.

成立 / 换届时间 Date	专业委员会 Specialty Committees
2023年3月28日成立 Establish on March 28, 2023	医药数字化及创新疗法专委会 Digital Medicine and Innovative Therapy Specialty Committee
2023年3月28日成立 Establish on March 28, 2023	创新医疗器械专委会 Innovative Medical Devices Specialty Committee
2022年11月1日换届 Changes on November 1, 2022	医药创新投资专委会 Pharmaceutical Innovation Investment Specialty Committee
2022年11月3日换届 Changes on November 3, 2022	医药企业合规专委会 Ethics and Business Compliance Specialty Committee
2022年12月10日换届 Changes on December 10, 2022	抗肿瘤药物临床研究专委会 Clinical Research on Oncology Drugs Specialty Committee
2023年3月29日换届 Changes on March 29, 2023	国际创新药物监管专委会 International Regulatory Science Specialty Committee
2023年3月30日换届 Changes on March 30, 2023	脑神经药物临床研究专委会 Clinical Research on Cranial Nerve Drugs Specialty Committee
2023年3月30日换届 Changes on March 30, 2023	医药政策专委会 Medicinal Policy Specialty Committee
2023年3月31日换届 Changes on March 31, 2023	心血管药物临床研究专委会 Clinical Research on Cardiovascular Drugs Specialty Committee
2023年5月11日换届 Changes on May 11, 2023	药物研发专委会 Drug R&D Specialty Committee
2023年7月20日换届 Changes on July 20, 2023	药物临床试验专委会 Clinical Trial Research Specialty Committee
2023年7月20日换届 Changes on July 20, 2023	创新研发服务专委会 Innovation R&D Services Specialty Committee
2023年10月29日换届 Changes on October 29, 2023	糖尿病与代谢性疾病药物临床研究专委会 Clinical Research on Diabetes and Metabolic Disease Drugs Specialty Committee



中国医药创新促进会
医药数字化及创新疗法专业委员会成立会议
Inaugurating Meeting of PhIRDA Digital Medicine and
Innovative Therapy Specialty Committee



中国医药创新促进会
创新医疗器械专业委员会成立会议
Inaugurating Meeting of PhIRDA Innovative Medical
Devices Specialty Committee



发挥专家资源优势，搭建跨界交流合作平台

Leverage the Advantages of Experts, Build a Platform of Exchanges and Cooperation Between Governments and the Industry

2022年12月7日，中国医药创新促进会医药创新投资专业委员会联合医药数字化及创新疗法专业委员会（筹）与香港联交所召开闭门座谈会，并形成《中国医药创新促进会关于特专科技公司上市制度的建议》正式提交香港联交所。

PhIRDA Pharmaceutical Innovation Investment Specialty Committee, Digital Medicine and Innovative Therapy Specialty Committee (preparatory), and the Stock Exchange of Hong Kong Limited (SEHK) held a closed-door symposium and submitted the *Suggestion from PhIRDA on Listing Rules of Specialist Technology Companies* to the SEHK on December 7, 2022.



2023年4月14-15日，由中国医药创新促进会糖尿病与代谢性疾病药物临床研究专业委员会主办的首届“中国糖尿病和代谢性疾病药物器械研发创新大会”在无锡召开。

PhIRDA Clinical Research on Diabetes and Metabolic Diseases Drugs Specialty Committee held the first “China Pharmaceutical and Medical Devices R&D for Diabetes and Metabolic Diseases Innovation Conference” in Wuxi on April 14-15, 2023.



纪立农 中国医药创新促进会糖尿病与代谢性疾病药物临床研究专业委员会主委、北京大学人民医院内分泌科主任
Ji Linong Chairman of Clinical Research on Diabetes and Metabolic Disease Drugs Specialty Committee, Director of Department of Endocrinology, Peking University People's Hospital



主题讨论
Panel Discussion

2023 年5 月12 日，由中国医药创新促进会药物研发专委会主办的“医药创新与发展论坛”在成都召开。

On May 12, 2023, PhIRDA Drug R&D Specialty Committee held the “Pharmaceutical Innovation and Development Forum” in Chengdu.



鲁先平 研发专委会主任委员、深圳微芯生物科技股份有限公司董事长兼总经理
Lu Xianping, Chairman of PhIRDA Drug R&D Specialty Committee,
Chairman of the Board & President of Shenzhen
Chipscreen Biosciences Co., Ltd.



2023年5月18日，中国医药创新促进会糖尿病与代谢性疾病药物临床研究专业委员会向CDE提交了协助制定的两项指导原则建议稿。

On May 18, 2023, PhIRDA Clinical Research on Diabetes and Metabolic Diseases Drugs Specialty Committee submitted proposed drafts of two guidelines to Center for Drug Evaluation (CDE) for assistance in formulation.



2023年6月4日，中国医药创新促进会抗肿瘤药物临床研究专业委员会联合北京市希思科临床肿瘤学研究会和杭州东方临床肿瘤研究中心共同发布《2022年度中国抗肿瘤新药临床研究评述》，并成功召开“2023 抗肿瘤创新药物临床研究论坛”。

On June 4, 2023, PhIRDA Clinical Research on Oncology Drugs Specialty Committee, CSCO Foundation and East Clinical Center of Oncology (ECCO) jointly published the 2022 Review of Clinical Research on New Anti-tumor Drugs in China, and successfully held the 2023 Clinical Research of Anti-tumor Innovative Drugs Forum.

2023年7月21日，由中国医药创新促进会医药政策专业委员会、药物临床试验专业委员会、医药企业合规专业委员会、创新研发服务专业委员会联合主办的“2023中国医药创新政策论坛”在北京召开。会议以“找准关键发力点 共建高质量发展新生态”为主题，以“制度创新”“技术创新”“协同创新”等为关键发力点，聚焦政策与创新高质量发展的薄弱环节，围绕基础研究与科研转化、临床试验水平提升、合规体系建设等议题开展深入探讨。

On July 21, 2023, PhIRDA Specialty Committees of Medicinal Policy, Clinical Trial Research, Ethics and Business Compliance, and Innovation R&D Services co-hosted the **2023 China Pharmaceutical Innovation Policy Forum** in Beijing. Under the theme of “Identify Driving Forces and Build a New Ecosystem for High-Quality Development”, the forum centered on key driving forces including institutional innovation, technological innovation, and collaborative innovation, and focused on policy and innovative high-quality development, with a particular focus on topics like basic research and research transformation, the improvement of clinical trials, and establishment of compliance systems.



胡 欣

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
Hu Xin, Chairman of PhIRDA Medicinal Policy Specialty Committee, Chief Pharmacist & Chief Expert of Pharmacy Department of Beijing Hospital



杨志敏

国家药品监督管理局药品审评中心副主任
Yang Zhimin, Deputy Director of CDE, NMPA



刘 力 北京市经济技术开发区管理委员会副主任

Liu Li, Deputy Director of the Beijing Economic and Technological Development Area (BDA)



王拥军 中国医药创新促进会脑神经药物临床研究专委会名誉主任委员
首都医科大学附属北京天坛医院院长
国家神经系统疾病临床医学研究中心副主任

Wang Yongjun, Honorary Chairman of PhIRDA Clinical Research on Cranial Nerve Drugs Specialty Committee, Dean, Beijing Tian Tan Hospital, Capital Medical University, Deputy Director, China National Clinical Research Center for Neurological Diseases



论坛现场
Forum

2023年7月27日，由中国医药创新促进会医药创新投资专业委员会、创新医疗器械专业委员会和医药数字化及创新疗法专业委员会联合主办的“第三届中国生物医药与器械创新投资人论坛”在深圳召开。

On July 27, 2023, PhIRDA Specialty Committees of Pharmaceutical Innovation Investment, Innovative Medical Devices, and Digital Medicine and Innovative Therapy, co-hosted the 3rd China Bio-Pharmaceutical and Medical Devices Innovation Investors Forum in Shenzhen.



圆桌讨论
Panel Discussion

07

热心公益，服务社会

>> Enthusiasm for Public Welfare, Passion for Serving the Society

8月9日-12日，由援助西藏发展基金会、西藏自治区卫生与健康委员会、拉萨市人民政府共同主办，我会协办的“西藏人人健康”2023年院士专家进藏义诊活动在拉萨市举行。会员单位积极响应，齐鲁制药、先声药业、悦康药业、复星医药等会员单位踊跃参加了本次义诊活动。

On August 9-12, 2023, Healthier Tibetans: 2023 Academicians and Experts Free Diagnosis, co-hosted by Tibet Development Fund, Healthcare Commission of Tibet Autonomous Region, People's Government of Lhasa Municipality, and organized by PhIRDA, was held in Lhasa. PhIRDA's members responded enthusiastically with Qilu Pharmaceutical, Simcere, Youcare Pharmaceutical, Fosun Pharma and other members participating in the free clinic.



大事记

Remarkable Events



中国医药创新促进会大事记(2022年10月-2023年12月)

2022

10月

10月12日

宋瑞霖执行会长拜访土库曼斯坦驻华特命全权大使巴拉哈特·杜尔德耶夫。

10月15日

“紫金医药合规论坛”系列线上活动第五期召开,主题为“医药营销合规专题”。

10月18日

我会参观和调研会员单位——普瑞基准科技(北京)有限公司。

10月22日

我会受邀参加第十一届亚洲监管大会,并分享我会参与ICH相关工作经验。

10月28日

我会参观和调研大钲资本和上海蔼睦医疗科技有限公司两家会员单位。

10月29日

由中国罕见病联盟和中国医药创新促进会主办的“2022年中国罕见病大会”在北京召开。

10月31日

全国政协参政议政特聘专家、我会执行会长宋瑞霖向政协全国委员会办公厅提交关于“全国政协2023年协商议题”的选题建议。

11月

11月1日

中国医药创新促进会医药创新投资专业委员会换届(第四届2022-2024)。

11月3日

中国医药创新促进会医药企业合规专业委员会换届(第二届2022-2024)。

11月7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——第五届虹桥国际健康科技创新论坛在上海举行。

11月10日

由香港特区政府及香港贸易发展局主办,我会作为重要战略合作伙伴支持的“第二届亚洲医疗健康高峰论坛”在香港召开。

11月11日

我会受邀参加国家药品监督管理局药品注册司召开的“药品注册申请电子申报工作座谈会”,反馈会员单位意见和建议。

11月15日

“紫金医药合规论坛”系列线上活动第六期召开,主题为“医药企业合规与免责机制探索”。



12月

12月7日

中国医药创新促进会医药创新投资专业委员会联合医药数字化及创新疗法专业委员会（筹）与香港联交所召开闭门座谈会，并形成《中国医药创新促进会关于特专科技公司上市制度的建议》正式提交香港联交所。

12月8日

宋瑞霖执行会长会见香港科技大学校长、中国科学院院士叶玉如。

宋瑞霖执行会长会见香港投资推广署署长 Stephen Phillips。

我会主办ICH指导原则系列培训正式启动，第一期主题为“药品注册电子申报及eCTD实施策略”。

12月10日

中国医药创新促进会抗肿瘤药物临床研究专业委员会在上海换届（第二届2022-2024）。

12月19日

我会向国家药品监督管理局提交关于“2023年药品监督工作计划”的反馈意见。

12月22日

ICH指导原则系列培训第二期成功举办，主题为“质量风险管理与药品全生命周期管理”。



12月26日

甘李药业股份有限公司、苏州映辉医药科技有限公司、南京优科生物医药股份有限公司加入我会。

12月29日

我会药物研发专业委员会主办的“医药创新说——2023年中国医药创新展望”线上召开。



2023

1月

1月3日

我会向国家医疗保障局医药价格和招标采购司递交“关于《新冠治疗药品价格形成指引意见》的反馈建议”。

1月10日

我会提出的《中国医药创新面临的挑战及其应对》建议报告在《改革内参》出版刊登。

1月11日

我会主办“充分发挥医药创新价值助力疫情防控”研讨会在京召开，并向中央全面深化改革委员会办公室递交《关于充分发挥医药创新价值助力疫情防控的建议》，同时抄报国家相关医药卫生主管部门。



1月17日

我会召开“创新药医保准入与创新支付研究”课题结题会。

1月18日

我会向农工党中央递交《做强做优做大我国生物医药产业 促进生物经济高质量发展》报告。

1月30日

我会受科技部委托,完成《我国制药产业发展现状、存在问题不足及发展对策建议》报告。

1月31日

我会向国家发展改革委递交《中国医药产业存在的卡脖子技术及解决策略》报告。

2月

2月6日

我会受邀参加《中药品种保护条例(修订草案征求意见稿)》省级药监部门、行业学/协会座谈会。

2月9日

我会受科技部委托,完成“中国十大疾病及其用药情况数据调研”工作并提交报告。

2月17日

ICH指导原则系列培训第三期成功举办,本期主题为“临床试验的规范与变革”。

我会与亚太医药交流中心签署合作备忘录。



2月20日-22日

我会秘书长冯岚带队,多名行业专家以及19家会员单位的代表一同组成调研团,参观调研包括中国科学院上海药物研究所在内的六家上海地区会员单位。

2月27日-28日

受中国香港特区政府相关机构邀请,我会组织22家会员单位访问香港科技大学、香港科技园、香港特区政府投资推广署、引进重点企业办公室,与特首政策组组长黄元山博士,财经事务及库务局局长许正宇,香港科技大学校长、中国科学院院士叶玉如进行会谈。

我会与香港科技大学签署合作备忘录,共同建立“大湾区生物医药国际创新中心”和“大湾区生物医药发展政策研究中心”。

2月28日

由我会、中国罕见病联盟以及RDPAC共同主办的“罕见病多层次保障两会代表座谈会”在京召开。

我会受邀参加国家药监局药品审评中心(CDE)举办的“以患者为核心的罕见疾病药物研发”研究课题调研会,并协助CDE向我会会员单位进行问卷调研。

3月

3月2日

我会年度会长李佳和执行会长宋瑞霖会见新加坡通商中国主席、前贸工部部长兼国家发展部高级政务部长李奕贤。

3月2日

受新加坡经济发展局邀请, 我会组织20家会员单位访问新加坡科技研究局、新加坡经济发展局及新加坡证券交易所等机构。

3月24日

信瑞诺医药(上海)有限公司、苏州宜联生物医药有限公司、丹诺医药(苏州)有限公司、广东众生药业股份有限公司、深圳市亦诺微医药科技有限公司、上海沃比医疗科技有限公司加入我会。

3月28日

中国医药创新促进会医药数字化及创新疗法专业委员会在苏州成立。

中国医药创新促进会创新医疗器械专业委员会在苏州成立。

3月29日-31日

由我会联合香港交易所、艾美达咨询、鼎新研究中心共同主办的“第七届中国医药创新与投资大会”在苏州召开。

3月29日

中国医药创新促进会国际创新药物监管专业委员会在苏州换届(第二届2023-2025)。

3月30日

中国医药创新促进会医药政策专业委员会在苏州换届(第四届2023-2025)。

中国医药创新促进会脑神经药物临床研究专业委员会在苏州换届(第二届2023-2025)。

3月31日

中国医药创新促进会心血管药物临床研究专业委员会在苏州换届(第二届2023-2025)。

4月

4月7日-8日

由我会主办的“溶瘤病毒创新药研究高峰论坛”在北京召开。

4月14日-15日

由中国医药创新促进会糖尿病与代谢性疾病药物临床研究专业委员会主办的首届“中国糖尿病和代谢性疾病药物器械研发创新大会”在无锡召开。

我会组织的“企业座谈研讨会”在无锡召开, 会议围绕国家药监局《关于加强对委托生产药品上市许可持有人监管工作的通知》(征求意见稿)和科技部《科技伦理审查办法(试行)》(征求意见稿), 听取参会企业代表反馈意见和建议。

5月

5月4日

我会举办“构建中国医药创新可持续发展生态环境座谈会”。

5月11日

中国医药创新促进会药物研发专业委员会在成都换届(第四届2023-2025)。

5月11日

我会在成都组织召开“会员单位交流座谈会”，来自成都地区部分会员单位和我会药物研发专委会的20余位会员单位代表参加会议。

5月12日

由中国医药创新促进会药物研发专委会主办的“医药创新与发展论坛”在成都召开。

我会执行会长宋瑞霖带队，参观调研康诺亚生物医药科技(成都)有限公司和四川三叶草生物制药有限公司。

5月15日

我会召开主题教育专题扩大会议，深入学习贯彻习近平总书记在深入推进京津冀协同发展座谈会上的重要讲话精神。

5月16、22-23日

我会组织评估专家组对北京市卫健委首批研究型病房示范建设单位北京大学肿瘤医院、北京协和医院、天坛医院、北京大学第一医院、中国医学科学院肿瘤医院、宣武医院等医疗机构进行实地勘察评估。

5月17日-18日

由香港特区政府和香港贸发局共同主办的第三届“亚洲医疗健康高峰论坛(ASGH)”在香港举行，我会作为本届论坛的全球支持伙伴深度参与论坛筹备工作。

5月19日

我会召开“优化创新药审评程序，缩短创新药上市进程调研座谈会”，时任CDE副主任周思源率调研组参会并听取企业建议。

6月

6月4日

中国医药创新促进会抗肿瘤药物临床研究专业委员会联合北京市希思科临床肿瘤学研究会和杭州东方临床肿瘤研究中心共同发布《2022年度中国抗肿瘤新药临床研究评述》，并成功召开“2023抗肿瘤创新药物临床研究论坛”。

6月8日

我会受邀参加国家发改委创新驱动发展中心关于“高技术产业2023年上半年发展形势分析研讨会”。

6月9日

我会举办北京首批研究型病房总结评估会，截至目前，已完成第一批研究型病房实地勘察、阶段评估。

6月9日-14日

ICH在加拿大温哥华举行工作组会议，我会7位专家通过线上和线下形式参加，参与各议题内容讨论与协调工作。

6月15日

我会向国家医保局提交《2023年国家基本医疗保险、工伤保险和生育保险药品目录调整工作方案》及相关文件公开征求意见的反馈意见稿。

6月16日

我会向农工党中央提交《关于推进生物医药现代化体系建设的建议》。



6月26日

上海赛立维生物科技有限公司、福建广生堂药业股份有限公司、康诺亚生物医药科技(成都)有限公司、苏州信达医疗器械有限公司加入我会。

7月

7月9日

我会受邀参加国家发改委一带一路建设促进中心关于“高质量共建‘健康丝绸之路’专家座谈会”。

7月12日

我会与山东省人民政府签署《医药创新发展合作协议》。

7月20日

中国医药创新促进会药物临床试验专业委员会在北京换届(第四届2023-2025)。

中国医药创新促进会创新研发服务专业委员会在北京换届(第三届2023-2025)。

7月21日

由中国医药创新促进会医药政策专业委员会、药物临床试验专业委员会、医药企业合规专业委员会、创新研发服务专业委员会联合主办的“2023中国医药创新政策论坛”在北京召开。

7月26日

我会执行会长宋瑞霖带队, 参观调研深圳君圣泰生物技术有限公司。



7月27日

由我会与龙华资本联合主办的“第三届中国生物医药与器械创新投资人论坛”在深圳召开。

7月28日

我会执行会长宋瑞霖带队, 参观调研深圳市亦诺微医药科技有限公司、深圳奥萨医药有限公司和国家高性能医疗器械创新中心。

7月29日

我会在珠海横琴召开“粤澳深度合作开发区生物医药产业发展交流会”。

7月31日

我会召开“中国创新器械审评审批制度改革”课题开题会。

8月

8月2日

国家金融监督管理总局人身保险监管部有关领导一行来我会调研, 听取商业健康保险与医药创新融合发展建议。

8月7日

我会向国家组织药品集中采购办公室提交《关于进一步规范国家组织药品集中采购投标企业行为的方案(征求意见稿)》的反馈建议。



8月9日-12日

由援助西藏发展基金会、西藏自治区卫生与健康委员会、拉萨市人民政府共同主办，我会协办的“西藏人人健康”2023年院士专家进藏义诊活动在拉萨市举行。

8月16日

我会召开2023联络秘书线上工作会议。

8月23日

我会召开“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”课题验收会。

8月24日

我会召开“建立中国特色的创新药支付保障体系研究”课题结题会。

8月25日

我会召开“药品上市许可持有人制度研究”课题结题会。

8月31日-9月1日

我会受邀参加北京市卫生健康委第二、三批研究型病房示范建设工作调度会。

9月

9月5日

我会执行会长宋瑞霖受邀参加“香港交易生物科技峰会2023”。



9月8日

我会执行会长宋瑞霖受邀参加由北京市人民政府和中国农工民主党中央委员会联合主办的“第一届国际生物医药产业创新北京论坛”。

我会执行会长宋瑞霖受邀参加由安徽省政府召开的生物医药产业发展研讨会，并深度分析安徽生物医药产业发展优势和潜力，对下一步发展目标、重点和路径提出建设性意见。

9月11日

欧洲制药工业协会联合会 (EFPIA) 代表团一行拜访我会。

9月19日

我会召开“探索以病人支付价和医保支付价为基础的创新支付体系研究”课题启动会。

我会受邀参加国家发改委体制改革综合司召开的“医疗卫生领域体制机制座谈会”。

9月21日

北京市卫生健康委党委书记、副主任钟东波带队到我会调研，听取关于进一步提升北京临床研究水平相关建议。

9月22日-24日

由我会指导，合肥综合性国家科学中心大健康研究院主办的“首届合肥生物医药创新与产业大会”在合肥召开。



9月25日

由我会、上海合作组织睦邻友好合作委员会、上海合作组织秘书处和哈萨克斯坦共和国驻华大使馆共同举办的“第二届上海合作组织医药合作发展大会”在苏州召开。

9月25日-27日

由中国国际经济交流中心指导,我会联合香港交易所、中国农工民主党中央健康中国建设工作委员会、艾美达咨询、鼎新研究中心共同主办的“第八届中国医药创新与投资大会”在苏州召开。

9月26日

我会举办粤港澳大湾区药械监管协同与创新发展主题政策论坛,粤港澳三地核心管理机构负责人首次齐聚,深入内地与NMPA相关领导共议协同监管。

我会组织上合组织相关国家医药卫生代表及驻华使领馆代表、重要外宾共37人参观了苏州生物医药产业园(BioBAY)及园区创新药企业。

10月

10月10日

清华大学药学院、深圳市高特佳投资集团有限公司、南京征祥医药有限公司、曙方(上海)医药科技有限公司、江苏谱新生物医药有限公司、北京昭衍新药研究中心股份有限公司、北京赛赋医药研究院有限公司、上海臻格生物技术有限公司加入我会。



10月12日

我会受国家药品监督管理局政策法规司委托,完成《医疗器械管理法》立法的反馈建议。

10月15日

“中国医药创新促进会2023年会长会议扩大会议”在深圳召开。

由我会和深圳市人民政府共同指导的“2023深圳市生物医药产业发展研讨会”在深圳成功举办。

10月28日-11月1日

ICH大会在捷克布拉格举行。5位我会推荐的IFPMA ICH专家现场参加了相关指导原则工作组会议。

10月29日

中国医药创新促进会糖尿病与代谢性疾病药物临床研究专业委员会在北京换届(第二届2023-2025)。

10月30日

国际医药企业联盟协会(INTERPAT)中国及大中华区主席、赛诺菲高级副总裁、全球知识产权负责人John Conway先生一行拜访我会。

11月

11月2日-3日

由BioCentury等单位主办,我会支持的“第十届中国医疗健康峰会”在上海召开。

11月4日

我会收到药品审评中心来函,商请协助2023年药品技术审评质量管理体系满意度调研,我会100家会员企业参与并完成问卷调查。

11月11日

中国药科大学国家药物政策与医药产业经济研究中心(简称NDPE)十周年年会成功召开。我会执行会长、NDPE执行副主任宋瑞霖在开幕式分享了“新形势下的中国医药创新”的主题报告。

11月16日

我会执行会长宋瑞霖受邀参加农工党中央组织召开的经济形势分析专家座谈会。

11月17日

由我会与海南广播电视总台(集团)共同主办的“2023中国国际生物医药大会”在海口召开。

11月24日

我会受国家医保局招采司邀请,参加挂网药品价格治理工作专题座谈会。

我会向国家药监局提交“关于精准支持小微企业,拉动生物医药发展新动能的专报”。

我会受北京市卫生健康委委托,就“创新药械入院使用”组织医药创新企业代表召开座谈会。

11月25日

由中国医药创新促进会医药企业合规专业委员会承办的中国医药行业监管与合规高峰论坛暨紫金医药合规论坛在苏州西交利物浦大学召开。

11月27日

我会受商务部邀请,参加进一步推进中国医药产品对外贸易高质量发展专题座谈会。

11月28日-30日

受日本制药工业协会(JPMA)及武田制药邀请,我会组织15家会员单位出访东京。访问期间,我会与JPMA共同主办中日医药产业项目对接会,拜访日本国立癌症研究中心、武田制药全球总部及日本湘南健康创新园(Shonan iPark)。

12月

12月2日

我会主办的“2023首届浦江生物医药源头创新论坛”在上海召开。

12月7日

我会收到国家药监局来函,对协会长期支持和关注国家药品监管事业作出的积极贡献表示感谢。同时,我会对2024年药品监管工作提交反馈,以推动转化为改革工作的具体政策和举措。

Remarkable Events of PhIRDA (October, 2022 - December, 2023)

2022

Oct

October 12

Executive President Song Ruilin met with Parakhat Durdyev, Ambassador Extraordinary and Plenipotentiary of Turkmenistan to the People's Republic of China.

October 15

The 5th Phase of "Zijin Pharmaceutical Compliance Forum" series of online activities with the topic of Compliance of Pharmaceutical Marketing was held virtually.

October 18

PhIRDA visited and inspected its member, Precision Scientific.

October 22

PhIRDA was invited to attend the 11th Asia Regulatory Conference (ARC) and share experience in ICH related work.

October 28

PhIRDA visited and inspected its members, Centurium Capital and AffaMed Therapeutics.

October 29

2022 China Conference on Rare Diseases, co-hosted by China Alliance for Rare Diseases (CARD) and PhIRDA, was successfully held in Beijing.



October 31

Song Ruilin, Executive President of PhIRDA, Expert of Talent Pool for State Affairs of Chinese People's Political Consultative Conference (CPPCC) submitted the suggestions for 2023 Topics of the CPPCC to the General Office of the National Committee of the CPPCC.

Nov

November 1

Election of the 4th PhIRDA Pharmaceutical Innovation Investment Specialty Committee (2022-2024) was held.

November 3

Election of the 2nd PhIRDA Ethics and Business Compliance Specialty Committee (2022-2024) was held.

November 7

The 5th 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 10

The 2nd Asia Summit on Global Health, co-hosted by the HKSAR Government and the Hong Kong Trade Development Council (HKTDC), and supported by PhIRDA as a Global Affiliate Partner, was successfully held in Hong Kong.



November 11

Invited by the Department of Drug Registration, National Medical Products Administration (NMPA), PhIRDA attended the Symposium on Electronic Application of Drug Registration and submitted suggestions and comments of PhIRDA's members.

November 15

The 6th Phase of “Zijin Pharmaceutical Compliance Forum” series of online activities with the topic of Exploration of the Compliance of Pharmaceutical Enterprises and Mzechanism of Accountability Exemption was held virtually.

Dec

December 7

PhIRDA Pharmaceutical Innovation Investment Specialty Committee, Digital Medicine and Innovative Therapy Specialty Committee (preparatory), and the Stock Exchange of Hong Kong Limited (SEHK) held a closed-door symposium, and submitted the *Suggestion of PhIRDA about Listing Rules of Specialist Technology Companies* to the SEHK following the symposium.

December 8

Executive President Song Ruilin met with Nancy Yuk-Yu, President of the Hong Kong University of Science and Technology, Academician of the Chinese Academy of Sciences (CAS).

Executive President Song Ruilin met with Stephen Phillips, Director-General of Investment Promotion at Invest Hong Kong (Invest HK).



December 8

Trainings for ICH Guidelines hosted by PhIRDA officially started. The topic of the 1st Phase was Electronic Application of Drug Registration and Strategies for eCTD Implementation.

December 10

Election of the 2nd PhIRDA Clinical Research on Oncology Drugs Specialty Committee (2022-2024) was held in Shanghai.

December 19

PhIRDA submitted suggestions on the 2023 Work Plan for Medical Products Administration to the National Medical Products Administration (NMPA).

December 22

The 2nd Phase of PhIRDA ICH Guideline trainings, themed Quality Risk Management and Pharmaceutical Product Lifecycle Management, was successfully held.

December 26

Gan & Lee Pharmaceuticals, Suzhou Yinghui Medical Technology Co., Ltd., and Nanjing YOKO Pharmaceutical Co., Ltd. joined PhIRDA.

December 29

“Pharmaceutical Innovation: 2023 Outlook of Pharmaceutical Innovation in China”, hosted by PhIRDA Drug R&D Specialty Committee, was held virtually.

2023

Jan

January 3

PhIRDA submitted the suggestions and comments on the *Guiding Opinions of the Pricing of COVID-19 Drugs* to the National Healthcare Security Administration.

January 10

PhIRDA's article *Challenges to China's Pharmaceutical Innovation and Its Response* was published on *the Reform Internal Reference*.

January 11

PhIRDA held the Seminar on Fully Leveraging the Values of Pharmaceutical Innovation for COVID-19 Response in Beijing, and submitted *Suggestions on Fully Leveraging the Values of Pharmaceutical Innovation for COVID-19 Response* to the General Office of the Central Committee for Deepening Overall Reform and departments related to healthcare and the pharmaceutical industry.

January 17

PhIRDA held the project closure meeting of the Research on Medical Insurance Access and Innovative Payment for Innovative Drugs.

January 18

PhIRDA submitted the Report of *Making China's Pharmaceutical Industry Stronger, Better, and Bigger, Promoting the High-Quality Development of the Bioeconomy* to the Central Committee of Chinese Peasants and Workers Democratic Party.

January 30

Entrusted by the Ministry of Science and Technology of the People's Republic of China, PhIRDA completed the *Report of Status Quo, Problems, and Suggestions on Development Strategies of China's Pharmaceutical Industry*.

January 31

PhIRDA submitted the *Report of Bottlenecks of Technologies in China's Pharmaceutical Industry and Tackling Strategies* to the National Development and Reform Commission.

Feb

February 6

PhIRDA was invited to participate in the symposium of drug regulatory departments at the provincial level and industrial associations on the *Draft Revision of Regulations on Protection of Traditional Chinese Medicine*.

February 9

Entrusted by the Ministry of Science and Technology of the People's Republic of China, PhIRDA completed the research on the Top 10 Diseases and Data of Drug Usage in China and submitted the report.

February 17

The 3rd Phase of PhIRDA ICH Guideline trainings themed Good Clinical Practice and Its Reform, was successfully held.

PhIRDA signed a Memorandum of Cooperation with Asia-Pacific Bio-Med Exchange Centre INC (APBMEC).

February 20-22

Led by Feng Lan, Secretary-General of PhIRDA, PhIRDA delegation consisting of experts and representatives from 19 members, visited 6 members in Shanghai, including Shanghai Institute of Materia Medica, Chinese Academy of Sciences.

February 27-28

Invited by the HKSAR Government and related institutions, PhIRDA organized a delegation composed of senior representatives from 22 members, visited the Hong Kong University of Science and Technology, Hong Kong Science & Technology Parks (HKSTP), Invest Hong Kong (InvestHK), and Office for Attracting Strategic Enterprises (OASES). PhIRDA delegation met with Dr. Wong Yuen Shan, Head of Chief Executive's Policy Unit, Christopher Hui, Secretary for Financial Services and the Treasury Bureau, and Nancy Yuk-Yu, President of the Hong Kong University of Science and Technology, Academician of the Chinese Academy of Sciences (CAS).

PhIRDA and the Hong Kong University of Science and Technology (HKUST) signed a Memorandum of Understanding (MoU), to jointly establish the "Greater Bay Area Center for International BioMed Innovations" and "Greater Bay Area Center for Policy Research on BioMed Development".

February 28

PhIRDA, China Alliance for Rare Diseases (CARD), and RDPAC co-hosted "Symposium of Deputies at the 'Two Sessions' on the Multi-Tiered Security for People with Rare Diseases".

Invited by Center for Drug Evaluation (CDE), PhIRDA participated in the project seminar "Patient-Centered Drug R&D for Rare Diseases" and assisted CDE to conduct a questionnaire among PhIRDA's members.

Mar

March 2

PhIRDA Annual Chairman Li Jia and Executive President Song Ruilin met with Lee Yi Shyan, Chairman of Business China and Former Minister of the Ministry of Trade and Industry Singapore and Senior Minister of State Ministry of National Development at Mandarin Oriental, Singapore.

Invited by the Singapore Economic Development Board (EDB), PhIRDA organized 20 members to visit institutions including the Agency for Science, Technology and Research (A*STAR), EDB, and Singapore Exchange (SGX).

March 24

SanReno Therapeutics, MediLink Therapeutics, TenNor Therapeutics, Zhongsheng Pharma, ImmVira, and Wallaby Medical joined PhIRDA.

March 28

PhIRDA Digital Medicine and Innovative Therapy Specialty Committee was established in Suzhou.

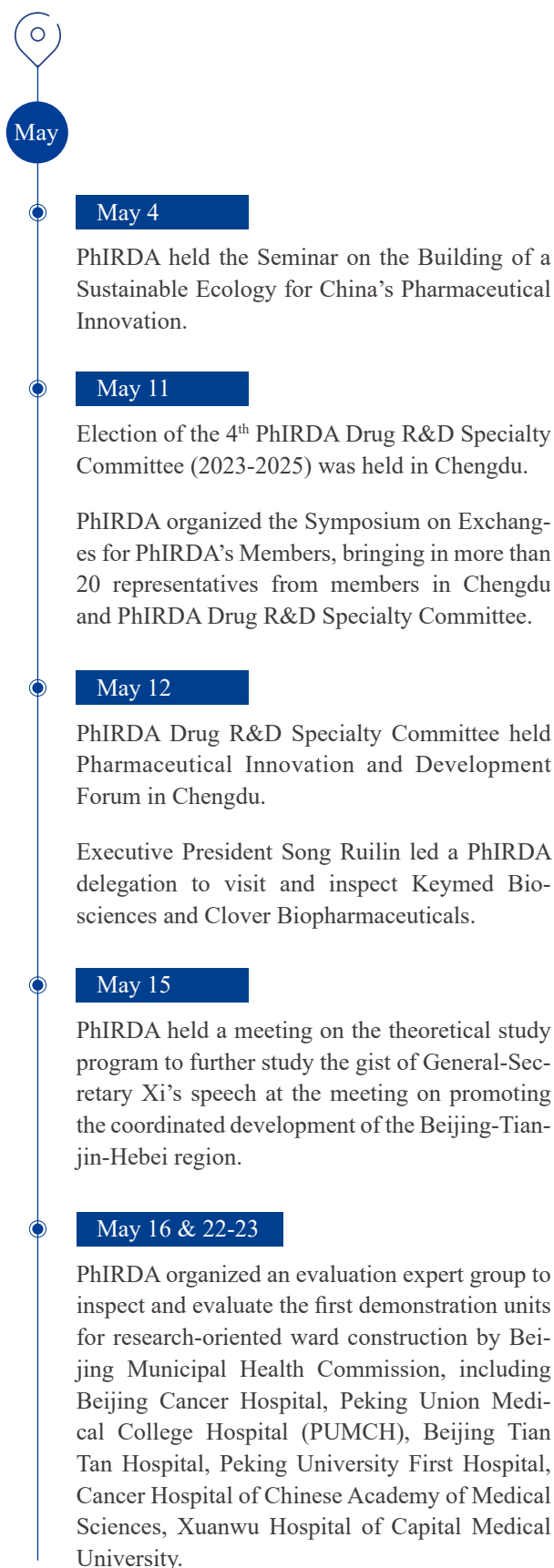
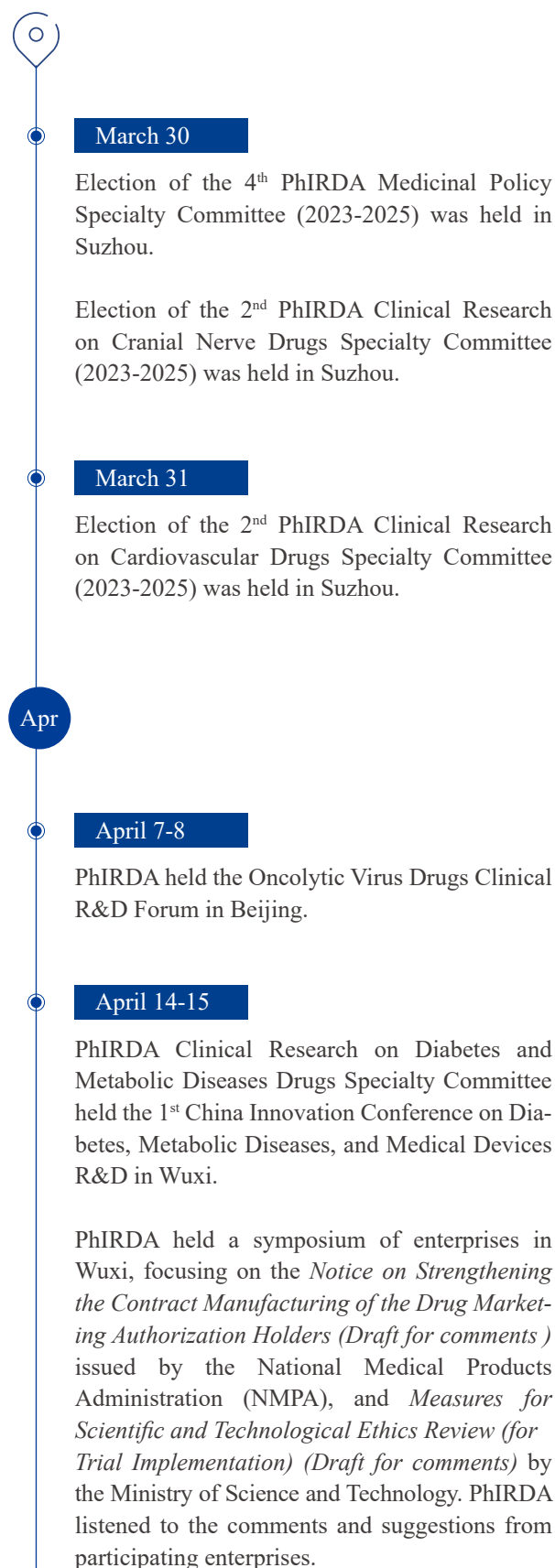
PhIRDA Innovative Medical Devices Specialty Committee was established in Suzhou.

March 29-31

The 7th China BioMed Innovation and Investment Conference, co-hosted by PhIRDA, Hong Kong Exchanges and Clearing Limited (HKEX), iMeta, and Ding Xin Pharmaceutical Innovation Research Center, was successfully held in Suzhou.

March 29

Election of the 2nd PhIRDA International Regulatory Science Specialty Committee (2023-2025) was held in Suzhou.





May 17-18

The 3rd Asia Summit on Global Health (ASGH), co-hosted by HKSAR Government and the Hong Kong Trade Development Council (HKTDC), was held in Hong Kong. As a global partner, PhIRDA deeply engaged in forum preparations.

May 19

PhIRDA held the Symposium on Improving the Procedure of Innovative Drugs Approval, Shortening the Marketing Process for Innovative Drugs. Zhou Siyuan, former Deputy Director of Center of Drug Evaluation (CDE), attended the symposium with an inspection group and listened to suggestions from enterprises.

Jun

June 4

PhIRDA Clinical Research on Oncology Drugs Specialty Committee, CSCO Foundation and East Clinical Center of Oncology (ECCO) jointly published the *2022 Review of Clinical Research on New Anti-tumor Drugs in China*, and successfully held the 2023 Forum on the Clinical Research of Anti-tumor Innovative Drugs.

June 8

PhIRDA was invited to attend the Seminar on Analyzing Development Trends of High-Tech Industries in the First Half of 2023 held by the Center for Innovation-Driven Development, National Development and Reform Commission.

June 9

PhIRDA held a conclusion meeting for evaluation of the first demonstration units for research-oriented ward construction. To date, the evaluation group has completed the on-site surveys and stage evaluation for the first demonstration units for research-oriented ward construction.



June 9-14

The ICH Assembly meeting was held in Vancouver, Canada. Seven IFPMA ICH experts recommended by PhIRDA participated in the meeting in-person or virtually, engaging in guidelines' discussion and harmonisation.

June 15

PhIRDA submitted the suggestions on *2023 Work Plan of Adjustments to the Catalog of Medicines Covered by the Basic Medical Insurance, Work-Related Injury Insurance, and Maternity Insurance* to the National Healthcare Security Administration.

June 16

PhIRDA submitted the *Suggestions on Advancing the Building of a Pharmaceutical Modern System* to the Central Committee of Chinese Peasants and Workers Democratic Party.

June 26

Shanghai Celliver Biotechnology Co., Ltd., Cosunter Pharmaceutical, Keymed Biosciences Inc., and SyMAP joined PhIRDA.

Jul

July 9

PhIRDA was invited by the Belt and Road Center of National Development and Reform Commission (NDRC) to attend an expert symposium on the High-Quality Building of a Health Silk Road Together.

July 12

PhIRDA signed a Pharmaceutical Innovative Development Cooperation Agreement with the People's Government of Shandong Province.



July 20

Election of the 4th PhIRDA Clinical Trial Research Specialty Committee (2023-2025) was held in Beijing.

Election of the 3rd Innovation R&D Services Specialty Committee (2023-2025) was held in Beijing.

July 21

PhIRDA Specialty Committees of Medicinal Policy, Clinical Trial Research, Ethics and Business Compliance, and Innovation R&D Services co-hosted the 2023 China Pharmaceutical Innovation Policy Forum in Beijing.

July 26

Executive President Song Ruilin led a PhIRDA delegation to visit and inspect HighTide Therapeutics, Inc.

July 27

PhIRDA and Longhua Investment co-hosted the 3rd China Pharmaceutical and Medical Devices Innovation Investor Forum in Shenzhen.

July 28

Executive President Song Ruilin led a PhIRDA delegation to visit and inspect ImmVira, AUSA Pharmed, and National Innovation Center for Advanced Medical Devices.

July 29

PhIRDA held the Exchanges for Development of the Pharmaceutical Industry in Guangdong-Macao in-depth Cooperation Zone in Hengqin, Zhuhai.



July 31

PhIRDA held a project kick-off meeting for Reform in China's Review and Approval System for Innovative Medical Devices.

Aug

August 2

Department for Personal Insurance Regulation, National Administration of Financial Regulation made an inspection tour of PhIRDA and listened to suggestions on the coordinated development of commercial health insurance and pharmaceutical innovation.

August 7

PhIRDA submitted suggestions on the Plan for Further Regulating the Companies' Bidding of Centralized Drug Procurement (Exposure Draft) to the National Office of Joint Medicine Procurement.

August 9-12

Co-hosted by Tibet Development Fund, Healthcare Commission of Tibet Autonomous Region, People's Government of Lhasa Municipality, and organized by PhIRDA, Healthier Tibetans: 2023 Academicians and Experts Free Diagnosis was held in Lhasa.

August 16

PhIRDA held 2023 Annual Contact Representatives Meeting virtually.

August 23

PhIRDA held a project closing meeting of A Comparative Research of R&D and Transformation Capability of Innovative Drugs in China and Abroad and Frontiers.



August 24

PhIRDA held a project closing meeting of Research on the Innovative Drugs Payment Security System with Chinese Characteristics.

August 25

PhIRDA held a project closing meeting of Research on the Mechanism of Drug Marketing Authorization Holders.

August 31- September 1

PhIRDA was invited to attend the scheduling meeting for the second and third groups of demonstration units for research-oriented ward construction held by Beijing Municipal Health Commission.

Sep

September 5

Executive President Song Ruilin was invited to attend HKEX Biotech Summit 2023.

September 8

Executive President Song Ruilin was invited to attend the 1st International Biomedical Industry Innovation Conference Beijing Forum, co-hosted by the People's Government of Beijing Municipality and the Central Committee of Chinese Peasants and Workers Democratic Party.

Executive President Song Ruilin was invited to attend the Symposium on Development of Pharmaceutical Industry held by the People's Government of Anhui Province, and thoroughly analyzed the advantages and potentials for local pharmaceutical industry's development, and provided valuable suggestions on goals, priorities and pathways for future development.



September 11

The European Federation of Pharmaceutical Industries and Associations (EFPIA) delegation visited PhIRDA.

September 19

PhIRDA held a project kick-off meeting of Research on the Exploration of the Innovative Payment System Based on Patients Payment and Medical Insurance Payment.

PhIRDA was invited to attend the Symposium on Systems and Mechanisms in Healthcare held by the Department of Comprehensive System Reform, National Development and Reform Commission (NDRC).

September 21

Zhong Dongbo, Secretary of the Party Committee and Deputy Director of the Beijing Municipal Health Commission, led an inspection group visited PhIRDA and listened to suggestions about further enhancing clinical research capacity in Beijing.

September 22-24

Guided by PhIRDA, the 1st Hefei Biomedical Innovation & Industry Conference was held by the Institute of Health and Medicine, Hefei Comprehensive National Science Center in Hefei.

September 25

The second Shanghai Cooperation Organization Pharmaceutical Cooperation Development Conference, co-hosted by PhIRDA, Good-Neighborhood, Friendship and Cooperation Commission of the Shanghai Cooperation Organization (GNFCC SCO), Secretariat of the Shanghai Cooperation Organization, and Embassy of the Republic of Kazakhstan in the People's Republic of China, was successfully held in Suzhou.



September 25-27

Under the guidance of the China Center for International Economic Exchanges (CCIEE), the 8th China BioMed Innovation and Investment Conference, co-hosted by PhIRDA, Hong Kong Exchanges and Clearing Limited (HKEX), the Healthy China Initiative Working Committee of the Central Committee of the Chinese Peasants and Workers Democratic Party, iMeta, and Ding Xin Pharmaceutical Innovation Research Center, was held in Suzhou.

September 26

PhIRDA held a forum focusing on the coordination and innovative development of pharmaceutical and medical devices regulation in the Guangdong-Hong Kong-Macao Greater Bay Area. Representatives of drug regulation departments from Guangdong, Hong Kong and Macao gathered for the first time, delving into the coordination of drug regulation with heads from National Medical Products Administration.

PhIRDA organized 37 representatives from pharmaceutical departments and embassies from the SCO countries to visit BioBAY and innovative pharmaceutical enterprises in Suzhou.

Oct

October 10

School of Pharmaceutical Sciences, Tsinghua University, GTJA Investment Group, Zenshine Pharma, Sperogenix Therapeutics, Jiangsu Hillgene, JOINN Laboratories, SAFE Pharmaceutical and Zencore Biologics Co., Ltd., joined PhIRDA.

October 12

Entrusted by the Department of Policies and Regulations, NMPA, PhIRDA submitted the feedbacks and suggestions for the legislation of the *Medical Devices Administration Law*.



October 15

2023 PhIRDA President Board Meeting was successfully held in Shenzhen.

2023 Shenzhen Bio-Pharmaceutical Industry Development Seminar, guided by PhIRDA and the Shenzhen Municipal People's Government, was successfully held in Shenzhen.

October 28-November 1

The ICH Assembly meeting was held in Prague, Czech Republic. 5 IFPMA ICH experts recommended by PhIRDA attended in person and participated in related ICH Task Forces meetings.

October 29

Election of the 2nd PhIRDA Clinical Research on Diabetes and Metabolic Diseases Drugs Specialty Committee (2023-2025) was held in Beijing.

October 30

John Conway, Chair of INTERPAT China & Greater Asia WG, Senior Vice President, Global Head of Intellectual Property, Sanofi, with Delegation from INTERPAT visited PhIRDA.

Nov

November 2-3

The 10th China Healthcare Summit, hosted by BioCentury, and supported by PhIRDA, was held in Shanghai.

November 4

Entrusted by Center for Drug Evaluation, NMPA, PhIRDA conducted a survey on the 2023 Drug Evaluation Quality Management System Satisfaction. 100 PhIRDA members participated and completed the questionnaire.

November 11

The 10th Anniversary Conference of the Research Center for National Drug Policy & Ecosystem (NDPE), China Pharmaceutical University, was successfully held. Song Ruilin, Executive President of PhIRDA and Deputy Executive Director of NDPE, addressed a keynote speech entitled “China Pharmaceutical Innovation under New Circumstances”.

November 16

Upon the invitation from the Chinese Peasants and Workers Democratic Party, Song Ruilin, Executive President of PhIRDA, attended the Expert Symposium on Economic Trends.

November 17

2023 China International Biopharma Conference, co-hosted by PhIRDA and Hainan Broadcasting Station (Group), was successfully held in Haikou.

November 24

Upon the invitation from the Department of Pharmaceutical Prices, Bidding and Procurement at the National Healthcare Security Administration, PhIRDA participated in the Drug Price Management Symposium.

PhIRDA submitted the *Report of Targeted Support for Micro and Small Innovative Companies, Driving New Momentum in the Development of the Pharmaceutical Industry* to NMPA.

Entrusted by Beijing Municipal Health Commission, PhIRDA organized representatives from innovative pharmaceutical companies to participate in the symposium on the Application of Innovative Medical Devices in Hospitals.

November 25

China Pharmaceutical Industry Regulation and Compliance Forum of Zijin Pharmaceutical Compliance Forum, organized by PhIRDA Ethics and Business Compliance Specialty Committee, was held in Xi'an Jiaotong-Liverpool University in Suzhou.

November 27

Upon the invitation from the Ministry of Commerce, PhIRDA participated in the Symposium on Further Advancing High-quality Development of China's Pharmaceutical Products in Foreign Trade.

November 28-30

Upon the invitation from Japan Pharmaceutical Manufacturers Association (JPMA) and Takeda, PhIRDA organized a delegation of 15 members to visit Tokyo. During the visit, PhIRDA and JPMA jointly held the SINO-Japan Pharmaceutical Industrial Meeting. PhIRDA Delegation visited National Cancer Center Japan, Global Headquarter of Takeda and Shonan Health Innovation Park (Shonan iPark).

Dec

December 2

2023 the First Pujiang Biopharmaceutical Original Innovation Forum hosted by PhIRDA was successfully held in Shanghai.

December 7

PhIRDA received the Thanks Letter from NMPA for PhIRDA's long-term support and positive contributions to the development of China's drug regulation. Meanwhile, PhIRDA submitted suggestions on the work of drug regulation in 2024, to promote the implementation of the specific policies and measures as part of the reform.

中国医药创新促进会章程

Constitution of PhIRDA



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、相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，但当选得票数不得低于总票数的2/3。

第三十一条 理事会每年至少召开1次会议，情况特殊的，可采用通讯形式召开。负责人调整不得以通讯会议方式进行决定。

第三十二条 经会长或者1/5的理事提议，应当召开临时理事会会议。

会长不能主持临时理事会会议，由提议召集人推举本会一名负责人主持会议。

第三节 会长会议

第三十三条 本会设立会长会议，由本会负责人组成。

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

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

第三十五条 会长会议行使以下职权：

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

第四节 负责人

第三十六条 本会负责人包括会长1名，副会长10-14名，秘书长1名。

本会实行年度轮值会长制度；会长从理事中经选举产生，任期1年。

本会负责人应当具备下列条件：

- (一) 坚持中国共产党领导，拥护中国特色社会主义，坚决执行党的路线、方针、政策，具备良好的政治素质；
- (二) 遵纪守法，勤勉尽职，个人信用记录良好；
- (三) 具备相应的专业知识、经验和能力，熟悉行业情况，在本会业务领域有较大影响；
- (四) 身体健康，能正常履责，年龄不超过70周岁，秘书长为专职；

(五) 具有完全民事行为能力;

(六) 能够忠实、勤勉履行职责,维护本会和会员的合法权益;

(七) 无法律法规、国家政策规定不得担任的其他情形。

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

第三十七条 本会负责人任期与理事会相同,连任不超过2届。

第三十八条 会长为本会法定代表人。

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

法定代表人代表本会签署有关重要文件。

本会法定代表人不兼任其他社团的法定代表人。

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

原任法定代表人不予配合办理法定代表人变更登记的,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。监事任期与理事会任期相同,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赔偿责任。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 Council.

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 Assembly 15 days in advance.

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

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

The Interim General Assembly shall be chaired by the Chairman. If Chairman is not 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 2022~2023 年度工作报告 暨 2024 年度工作建议

2022~2023 Annual Work Report & 2024 Work Proposal for China Pharmaceutical Innovation and
Research Development Association



中国医药创新促进会2022~2023年度工作报告 暨2024年度工作建议

(2024年2月22日第十一届理事会第五次会议)

各位理事：

习近平总书记多次强调，生物医药产业是关系国计民生和国家安全的战略性新兴产业，要加强基础研究和科技创新能力建设，把生物医药产业发展的命脉牢牢掌握在我们自己手中。在国家“创新驱动”发展战略等政策的指引下，我国生物医药行业经过十几年的发展，科研创新能力不断提升、市场规模不断扩大，取得了令人瞩目的成绩。但是，在原始创新、成果转化等方面依然面临非常大的挑战；由于地缘政治以及全球经济衰退，叠加国内医保准入和医院用药等市场制度的不完善，致使生物医药创新投资大幅下降，一些研发型创新企业发展受到严重影响。作为推动生物医药行业高质量发展的协会，药促会全面贯彻落实党的二十大精神，始终密切关注国家政策动态，深入了解产业发展需求，扎实开展多样丰富的工作，为我国社会经济发展和人民健康贡献力量。我会2022~2023年度重点工作完成情况如下：

第一部分 2022~2023年度主要工作回顾

自2022年9月22日第十一届理事会第四次会议召开以来，我会坚持以党建为引领、以创新为核心、以问题为导向、以服务为根本，聚焦行业发展的“卡脖子”问题推进医药政策研究，搭建产业界多领域、多形式的交流合作平台，推动我国医药产业国际化进程等，工作成果显著并得到社会多方关注和行业普遍认可。

一、以习近平新时代中国特色社会主义思想为统领，强党性、谋发展、做贡献，稳步推进协会各项工作高质量发展

过去一年，我会党支部在上级党委的正确领导下，坚持以习近平新时代中国特色社会主义思想为指导，认真贯彻落实新时代党的建设总要求和党的组织路线，以党的政治建设为统领，以党组织标准化规范化管理为抓手，以深化党风廉政建设为保证，围绕“强党性、谋发展、做贡献”的中心思想，认真有序开展党建工作。报告期内，我会党支部积极发展2名预备党员，党员总人数增至12名。2023年4月至8月，我会党支部积极开展“学习贯彻习近平新时代中国特色社会主义思想”主题教育，全面落实中央主题教育“学思想、强党性、重实践、建新功”12字总要求。通过理论学习、调查研究等学习实践，开展主题教育活动已成为推动协会各项工作的重要抓手。此外，我会严格按照“我为群众办实事”的工作部署，在提升患者用药可及性和产业创新健康发展方面积极探索，服务行业、服务群众。

二、充分发挥高端智库作用，积极开展医药政策与战略专题研究，向中央多个部委提交建议举措，为我国医改事业、医药科技发展、完善医药政策和产业发展建言献策

(一) 针对疫情防控出现的抗新冠病毒新药审批与供应的不平衡，我会组织专家学者及产业代表召开专题研讨会并形成一致共识，形成《充分发挥医药创新价值，助力疫情防控》建议报告递交至中央全面深化改革委员会，同时抄送国家发改、工信、科技、卫生、

医保以及药监等六个主管部门。

(二) 高度关注医药创新政策协同产业高质量发展,以调查研究为主,完成多项国家政府部门委托的研究专题:

一是完成科技部委托的《我国制药产业发展现状 存在的问题不足及对策建议》《中国十大疾病及其用药信息调研》报告;农工党中央委托的《做强做优做大我国生物医药产业 促进生物经济高质量发展》《关于推进生物医药现代化体系建设的建议》专题研究报告;国家发改委调研的《中国医药产业存在的卡脖子技术及解决策略》以及《“十四五”生物经济发展规划》中期评估等专题研究工作。

二是针对持续深化药品监管制度改革,向国家药监局提交《2023年药品监管工作计划》《2024年药品监管工作计划》《关于创新医疗器械产业支持政策》《关于医疗器械管理法立法》等反馈建议。

(三) 持续关注特殊人群用药保障问题,总结相关领域改革成果、推动和宣传罕见病立法和儿童药相关制度建立和优化,以期建立激励罕见病、儿童药药物研发和供给、患者诊疗、报销与支付等完善的法律和制度体系,多维度满足罕见病患者、儿童的用药需求。

三、洞察产业共性问题,高质量开展课题研究,推动政策体系完善和医药创新环境改善

(一) 聚焦“产学研医”全产业链深度结合,积极承接政府委托课题,为营造和构建良好的医药创新技术成果转化政策及市场环境提供支撑

一是高质量完成科技部重大专项司委托的“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,聚焦推动关键核心技术攻关和成果转化,重点梳理我国创新药物研发重点单位(包括高校、科研院所和企业等)的优势技术,量化分析各项技术的发展水平和国内外差距。通过对会员单位的优势技术

进行调研、组织“创新药物研发颠覆性技术企业青年科学家座谈会”等,全面了解和分析我国高校和科研院所在原始创新、成果转化、人才规模与质量等方面存在的问题与挑战并提出政策建议,为促进医药创新转化和产业高质量发展提供参考。

二是受北京市卫健委委托,开展“北京市研究型病房示范单位建设动态评估”工作,深入调研和全面分析了首批10家示范单位自2020年建设以来取得的成效,形成总结评估报告及政策建议。其中,推动研究者发起临床研究、加强专病专科的医研企临床研究联合体建设、加快创新成果入院等政策建议被相关部门采纳并印发《进一步提升北京市临床研究水平若干措施的通知》等重要文件;接续开展第二、三批研究型病房建设动态评估,以评估促建设,提升医疗卫生机构临床研究水平和产业发展。

(二) 围绕行业发展的痛点堵点问题,自主开展课题研究,以期攻克“卡脖子”难题,补齐发展短板

一是重点关注持续优化的医保目录续约调整规则,开展“创新药医保准入和创新支付”研究,为创新药全生命周期证据积累、可持续发展奠定基础。

二是开展“建立中国特色的创新药支付保障体系”研究,从体系建设的顶层设计、创新药价值实现、基本医保准入制度、多层次保障体系与多元创新支付等维度提出建议。

三是合作开展“参照药品遴选方法学共识”研究,以参照药品遴选操作规范与实践相结合形成共识,助力卫生技术评估和循证决策证据水平的整体提升。

四是聚焦器械审评管理体制机制以及合理资源配置问题,开展“中国创新器械审评制度改革”研究,探索推进我国监管体系和能力现代化,助力医疗器械产业高质量、独立自主发展的创新路径。

五是开展“药品上市许可持有人制度研究”课题,进一步厘清MAH制度实施过程中影响整体创新资源的高效运用和制约中国药企国际化进程的关键症结,推进MAH制度在中国更好地稳固实施。

六是开展“中国创新药出海技术路径研究”课题，聚焦于一体化程度相对较高、经济发展水平具有相当潜力的东盟国家，研究和推进“药监注册技术路径和标准共识”，推动与东盟国家建立双边/多边协议，逐步实现临床试验数据、审评、检查、检验标准和结果的共享与互认，以推进国产创新药出海与国家相关部门战略的融合与链接，推动出台有利于创新药出海的政策，加速推动我国医药创新产品实现国际化。

四、发挥政府与行业联系的桥梁纽带作用，广泛征求产业意见，参与重要政策法规学习与修订、制定工作，推动政策体系完善和医药创新环境改善和行业发展

(一) 针对《药品管理法实施条例(修订草案征求意见稿)》《中药品种保护条例(修订草案)》，我会积极征询会员单位意见，并在国家药监局召开的修订讨论会上集中反馈。

(二) 对于《科技伦理审查办法》《关于加强委托生产药品上市许可持有人监管工作的通知》等法规文件，我会组织会员单位召开讨论会，提出避免重复审查、缩短研发周期、充分保护企业合法权益、鼓励省级管理机构开展更为灵活的区域监管等具有实操性和产业指导意义的建议，其中多项内容被相关部门采纳，并列入正式文件中发布。

(三) 建立政企沟通平台，拓宽政企合作渠道。协助科技部开展关于医药发展战略系列调研；协助CDE开展药品审评及ICH指导原则培训计划问卷调查；受邀参加国家医保局《新冠治疗药品价格形成指引(试行)》征求意见稿座谈会，表达产业重点关切；组织会员单位参加CDE有关课题及系列研讨会，如“以患者为核心的罕见疾病药物研发”等；积极参加由相关政府部门召开的各类研讨座谈会，反馈行业意见和建议，包括罕见病多层次保障两会代表座谈会、推进生物医药现代化体系建设专题研讨会、优化创新药审评

程序/缩短创新药上市进程调研座谈会、高技术产业2023年上半年发展形势分析研讨会、医疗卫生领域体制机制座谈会等。

五、积极拓宽发声渠道，加强沟通交流，扩大影响力

一是针对行业关切问题组织开展企业及专家座谈会交流会，如构建中国医药创新可持续发展生态环境座谈会等。

二是根据产业发展的最新情况和研究成果，发表学术文章、出版研究报告，为政策制定提供科学依据和参考。如研究成果《中国医药创新面临的挑战及其应对》被《改革内参》收录，在《中国医药报》发表《2022年我国罕见疾病药品获批情况盘点》，以及在《世界临床药物》发表《中国临床试验数据监管改革的分析与思考》等。

六、深入开展国际医药交流，推动全球医药产业交流与合作

(一) 积极参与国际规则制定，组织专家参与药品监管标准指导原则制修订工作，推动ICH指导原则在中国落地转化实施。

一是作为国际药品制造商协会联合会(IFPMA)成员，我会自2017年至今已向IFPMA 25个ICH工作组推荐50名专家(包括14名组长，12名候补组长)。报告期内，我会推荐的专家在IFPMA全球专家总人数中占比超过53%。

二是受国家药品监督管理局ICH工作办公室委托，我会针对73个ICH指导原则向会员单位征求建议，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，受国家药品监督管理局药品审评中心委托，我会积极开展ICH指导原则专家工作组的招募工作，报告期内，已有107位我会推荐的专家被纳入35个CDE ICH专家工作组中。

三是我会邀请多位业界专家围绕药品注册电子

申报及eCTD实施策略、质量风险管理与药品全生命周期管理、临床试验的规范与变革等主题,从产业角度做深度解读与分享,帮助企业更好地适应已实施及即将实施的ICH指导原则。

四是2023年ICH大会继疫情三年后首次恢复线下召开,5位经我会推荐的IFPMA ICH专家参加各指导原则工作会议,为加快监管规则的协调与统一,推进国际监管互认,共促全球医药产业发展做出积极贡献。

(二)加强与“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。

2023年3月29日下午,我会举办第七届中国医药创新与投资大会国际医药创新合作论坛。国家药品监督管理局党组成员、副局长徐景和,乌兹别克斯坦高等教育、科学与创新部副部长图尔迪库洛娃,乌驻华使馆总领事亚赫亚耶夫出席论坛并致辞。

2023年9月25日下午,我会会同上海合作组织睦邻友好合作委员会、上海合作组织秘书处、哈萨克斯坦共和国驻华大使馆共同主办第二届上海合作组织医药合作发展大会。来自伊朗、哈萨克斯坦、吉尔吉斯斯坦、巴基斯坦、俄罗斯、乌兹别克斯坦、阿塞拜疆、柬埔寨、缅甸、阿联酋等10个上合组织相关国家的近30位医药卫生、科技创新部门的负责人和高级别代表、专家专程赴华参会。与会各国共同发布了《苏州倡议》,为构建更加紧密的上合组织命运共同体注入新的强劲动力。

(三)与各国使领馆、行业协会和国际组织开展交流及出访活动,分享中国药监成就,促进国际产业交流,推动全球医药产业合作共赢。

我会始终积极拓展国际事务新合作、开拓新伙伴,与美、加、英、澳、日、荷、丹麦、西班牙、瑞士、芬兰、意大利、白俄罗斯、乌兹别克斯坦、土库曼斯坦、以色列、新加坡等国家驻华使领馆及相关机构,以及

IFPMA、APAC、上合组织秘书处等国际组织保持紧密联系;与亚太医药交流中心、香港科技大学签署合作备忘录,共同推动全球医药产业相互交流与合作。

我会受邀参加第十一届亚洲监管大会、第二/三届亚洲医疗健康高峰论坛、第十届中国医疗健康峰会、2023亚洲健康与生命科学创新合作峰会等国际会议,充分展示中国药品监管改革和医药创新发展成果,对于增进世界与我国医药创新领域的沟通、了解和认同具有重要作用。

2023年2月26日—3月5日,我会组织医药企业高级别代表团访问中国香港、新加坡,拜访两地政府相关机构及科研创新部门,实地考察当地创新产业园区,并组织医药产业交流会。本次出访成功推动我会多家会员单位入驻香港科学园,借助香港科学园区的人才优势提升创新科研成果转化率,深度融入国家科技创新战略中。

2023年11月28日—30日,我会组织医药企业高级别代表团访问日本,与日本制药工业协会(JPMA)共同主办中日医药创新项目对接会,拜访日本国立癌症研究中心,实地考察武田制药及湘南健康创新园,为加强中日医药产业合作交流,助力中国创新医药企业“出海”日本及亚太地区作出了积极贡献。

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

(一)中国医药创新与投资大会

2023年3月和9月,我会联合相关机构共同主办两届中国医药创新与投资大会。两届大会各具特色、别具匠心,第七届首设近万平米“临床研究和药械创新”专题展区、第八届继疫情之后首次恢复国际交流合作业务板块;两届大会根据实时热点打造多场差异互补的特色化论坛,且在项目筛选、议程策划、互动体验、人才服务、招商引资等方面不断优化升级、开拓创新,帮助参会各方实现信息互通、合作互利,成果互惠。

（二）2022中国国际进口博览会——第五届虹桥国际健康科技创新论坛

2022年11月6日，我会与国家卫健委国际交流中心在2022年进博会期间共同主办第五届虹桥国际健康科技创新论坛。论坛以“聚创新突破，筑健康未来”为主题，来自政府、产业、临床和科研机构以及投资界的领导及国内外专家代表齐聚一堂，共同探讨如何以国际合作推动健康科技创新，应对重点疾病和公共卫生领域的挑战，助力健康中国建设，共筑全球健康福祉。

（三）中国罕见病大会

2022年10月和2023年10月，我会与中国罕见病联盟在北京联合主办两届中国罕见病大会。大会聚焦罕见病领域基础研究、诊疗、保障、产业发展等核心议题，多维度展示我国罕见病领域前沿热点与科技创新能力，助力我国罕见病防治与保障事业迈上新台阶。

（四）溶瘤病毒创新药研究高峰论坛

2023年4月8日，我会主办的溶瘤病毒创新药研究高峰论坛在北京举办。论坛聚焦溶瘤病毒创新药研究，来自溶瘤病毒领域的专家、研究者、企业家、服务机构从业者等共聚一堂，透过最新临床数据与研发进展，多角度解读产业发展趋势，为促进溶瘤病毒创新药临床研究与应用转化贡献力量。

（五）2023中国国际生物医药大会

2023年11月17日—18日，我会和海南广播电视台总台（集团）共同主办2023中国国际生物医药大会。会议设置中国国际生物医药创新高峰论坛、创新药政策准入分享论坛、全球肿瘤药物研发高峰论坛和药械创新研发路演，聚焦医药创新政产学研用资各环节痛点，邀请各方专家学者进行研讨和交流，为促进医药产业交易和项目投资，引领医药产业制度集成创新，打造高端商贸合作平台，推动医药产业高质量发展贡献力量。

（六）2023首届浦江生物医药源头创新论坛

2023年12月2日，我会主办的2023浦江生物医药源头创新论坛在上海召开。论坛聚焦“激活源头创新第一公里”，邀请国内外顶尖高校科研院所的院士和科学家、临床研究领军专家，政策制定者、头部风险投资机构合伙人以及创新企业领袖聚一堂，从科学发现、科学转化、投资孵化、企业赋能、政策指引等多维度探讨源头创新的关键点和路径，共话如何摆脱产业“内卷”困局，为产业增长培育激发创新动能。

八、不断汇聚高端资源要素，推动分支机构工作有序进行，探索搭建主题化、常态化、品牌化的特色活动平台，为推动我国药械产业高质量和可持续发展贡献新的力量

报告期内，我会正式成立创新医疗器械、医药数字化及创新疗法2个专业委员会，完成11个专业委员会换届任务。依托分支机构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7大方面开展了大量卓有成效的工作。

（一）积极助力药械全产业链上下游协同发展，代表药械创新主体发声。

一是专业委员会积极参与政府部门法律法规和指导原则的制定和修订工作，形成多项研究成果和政策建议报告并上报国家有关部门，相关意见和建议得到采纳。2023年5月，糖尿病与代谢性疾病药物临床研究专业委员会专家起草完成《1型糖尿病非胰岛素药物研发技术指导原则》《钳夹试验评价胰岛素药代动力学和药效动力学指导原则》两项指导原则建议稿，并提交国家药监局药品审评中心。

二是跨界参与资本市场制度改革，为打通专精特新公司上市融资之路贡献应有力量。2022年12月7日，医药数字化及创新疗法和医药创新投资专业委员会组织港交所、拟上市企业、投资机构、券商、律所和会计师事务所等市场各参与方和相关专家学者，就港交

所“18C”上市章节具体条款和设计初衷交换意见并深入研讨,形成《关于特专科技公司上市制度的建议》递交港交所。相关建议在港交所2023年3月24日发布的制度中相应体现。

三是聚焦临床需求,为提升患者用药可及性、降低企业研发成本贡献力量。2023年4月11日,脑神经药物临床研究专业委员会组织专家召开临床需求论证会,就相关药品临床实际治疗需求情况开展论证并向国家药监局药品审评中心致函,建议加速引入相关药品的原研药物进入中国市场。相关药品已得到豁免临床引入中国的许可。

(二) 扎实开展基础性研究,引导构建可持续发展的良性药械创新生态环境。

抗肿瘤药物临床研究专业委员会定期针对热门靶点及其药物作用机制和国内研发现状进行全面梳理,于2023年6月发布《2022年度中国抗肿瘤新药临床研究评述》,引导药物研发科学、理性、有序发展。

(三) 心系患者临床需求,联合临床机构和产业主体,为满足患者临床用药需求贡献绵薄之力。

脑神经药物临床研究专业委员会先后联合我会会员单位天坛医院、百济神州、双鹤药业等,开展相关临床研究和上市后临床试验服务,为满足患者临床用药需求贡献力量。

(四) 不断加强法制合规建设,动态提升行业标准,呼吁构建良性合规的药械产业发展生态环境。

根据合规领域相关法律规定和国际准则的最新变化,医药企业合规专业委员会对《中国医药创新促进会医药企业伦理准则》(拟于2024年发布)进行修订和完善,为规范会员单位及相关人员从业行为,促进药械产业健康有序发展提供依据。

(五) 汇聚不同专业领域专家力量,为促进整个药械产业跨界交流和创新发展搭建品牌化、专业化学术活动平台。

1. 中国糖尿病和代谢性疾病药物器械研发创新大会

2023年4月14日,由糖尿病与代谢性疾病药物临床研究专业委员会主办的中国糖尿病和代谢性疾病药物器械研发创新大会在无锡举办。会议以糖尿病和代谢性疾病临床需求为抓手,聚焦高发病症,围绕糖尿病、肥胖、NASH、骨质疏松、痛风、投资与合作、研究设计与方法、能力建设培训等领域设置专题论坛。

2. 中国医药创新政策论坛

2023年7月21日,由医药政策、药物临床试验、医药企业合规和创新研发服务专业委员会联合主办的2023中国医药创新政策论坛在北京举办。论坛关注医药政策与产业创新和高质量发展的薄弱环节,设置创新药准入实践与探索、高质量临床研究发力原始创新、新技术赋能临床试验提质增效等主题论坛,聚焦基础研究与科研转化、临床试验水平提升、合规体系建设等议题,为破除监管、市场准入、落地使用等领域机制障碍,畅通创新成果转化渠道,全面激发我国创新主体源头创新能力和活力赋能。

3. 中国生物医药与器械创新投资人论坛

2023年7月27日,由医药创新投资、医药数字化及创新疗法和创新医疗器械专业委员会联合主办的第三届中国生物医药与器械创新投资人论坛在深圳成功举办。论坛以“信息技术和金融服务与药械产业跨界融合创新”为主题,撬动金融资本、信息技术、药械产业三界融合创新发展,合作共赢。

此外,我会相关分支机构还主办了医药创新与发展论坛、2023抗肿瘤创新药物临床研究论坛,中国医药行业监管与合规高峰论坛,中国医药创新与投资大会相关分论坛和心血管领域创新药物临床研究学术交流等丰富多元的业务活动,为药械产业生态环境建设加持助力。

(六) 创新活动方式,开展传播灵活、受众更广的线上业务活动,代表医药创新全链条发声。

2022年10月—12月,医药企业合规和药物研发专业委员会先后举办了“紫金医药合规论坛——医药企业合规与免责机制探索”和“医药创新说——2023年中国医药创新展望”主题直播活动,联合相关合作单位和媒体对直播活动进行全方位宣传报道和推流转播,在积极响应疫情防控政策的同时持续为药械产业发声。

九、充分发挥产业资源优势,与地方有关部门及专业机构建立紧密联系,深化与地方政府及产业园区业务联动,共同服务中国医药产业改革、创新、发展大局

近年来,我会积极探索与地方政府、产业园区等多方跨界合作、融合发展新模式,围绕如何盘活药械产业发展的存量空间、拓展增量空间开展了大量研究和基础性工作。2022年10月以来,我会与北京、上海、深圳、成都、温州以及江苏、安徽、山东等各省市级地方政府相关部门保持紧密联系,为构建世界一流高科技园区和现代化生物医药制造业集群提供智力支持。

十、全面加强和提升会员服务工作能力 and 水平,增强会员单位“获得感”与凝聚力

(一) 不断完善会员体系建设,充分激发内部活力。

会员单位是我会重要的体系组成。在不断提升会员凝聚力、提高会员服务质量的的同时,我也会在积极挖掘更多优秀创新主体,优化完善会员结构。经通讯理事会表决,报告期内,我会共吸纳21家新会员,截至目前,我会共有各类会员单位183家,涵盖医药企业、器械企业、科研院所、临床研究机构、创新服务机构和医药投资机构等全产业链条。此外,还有3家单位的入会申请将在本次会议上提请各位理事审议,详情请见“发展会员单位的议案”。

(二) 积极联动各方资源,丰富会员活动形式,共谋产业发展新未来。

为深入了解会员单位发展动态,加强会员间的横向联动,促进产业深度交流与合作,我会通过召开线上线下专题座谈会、调研参观会员单位以及组织会员之间的交流互访等会员活动,不断增强行业信息的传递,为会员各主体间的合作搭建平台、创造可能。2023年,我会在上海、苏州、成都、深圳等地组织召开区域性会员交流座谈会,由会领导带队联合行业专家分别走进16家会员单位进行参观调研。

(三) 积极开展会员宣传服务工作,搭建会员动态品牌推广平台。

自2023年起,我会定期收集会员单位的重大成果及重要事项(审评审批结果、研发进展、投融资及战略合作等),以会员动态集锦(2023年已发布46期)的形式为会员单位提供日常宣传服务;同时,持续关注会员单位发展动向,以重要里程碑事项为抓手进行专题报道。以上内容通过我会官方公众号、网站等自有平台以及外部合作的优质媒体渠道进行对外发布,充分展现了我国优质创新主体的发展风貌。

(四) 发挥行业协会的职能和作用,进一步提升会员服务的内容和能力,伴随会员单位同频成长。

鉴于国家和各地方政府对企业申报相关项目、奖项等需行业协会出具专业性的推荐或证明文件,本着对政府、企业负责的原则,经会员单位申请及各方审慎评估论证,我会年度内为多家会员单位出具国家级专精特新小巨人、新冠药首发价推荐、绿色工厂项目等相关证明材料,助力会员单位申报荣誉,保护会员单位合法权益。

十一、践行医药行业社会责任,全力推动援藏工作

2023年8月9日—12日,由援助西藏发展基金会、西藏自治区卫生健康委员会、拉萨市人民政府共同主

办,我会协办的“西藏人人健康——2023年院士专家进藏义诊”活动在拉萨举行。齐鲁制药、先声药业、悦康药业、上海医药、复星医药等多家会员单位积极响应、踊跃参与。此次活动由全国21个省份、39个城市的相关领域院士、国内知名三甲医院心血管学科专家及骨科、妇科、中医科等217位专家和志愿者参与,医疗团队分为6个小组,分别赶赴城关区、堆龙区、达孜区、曲水县、林周县等地区开展诊疗活动,为增强广大藏区老百姓的健康管理意识,有效改善西藏人民健康状况和生活质量贡献力量。药促会及相关会员单位也受到援助西藏发展基金会理事长班禅大师的高度认可和称赞。

各位,在药促会全体同仁的共同努力奋斗下,我会已经成为推动生物医药行业高质量发展的重要社会力量。在此衷心感谢全体会员单位、分支机构委员的信任、支持与帮助!今后我们将继续发挥药促会的平台优势,秉承办会宗旨,在坚持党的领导下,为改善我国医药产业生态环境、推动生物医药行业创新发展、提升我国在全球生物医药领域竞争力等方面奋楫笃行。新的一年,药促会着重围绕以下几个方面开展相关工作:

第二部分 2024年度重点工作建议

一、继续加强党组织建设,进一步加强理论知识学习,为建设具有影响力的行业协会提供坚强组织保障

新的一年,我会将继续把学习贯彻习近平新时代中国特色社会主义思想作为全部工作的主题主线、贯穿全部工作始终,认真学习党的二十大精神和习近平总书记系列重要讲话精神,夯实理论基础,锤炼良好作风;充分利用“三会一课”“主题党日”等活动,切实发挥党组织的政治领导作用和战斗堡垒作用,着力提升政治把握能力、统筹谋划能力、调查研究能力、联系群众能力,从协会角度以真挚情怀不断增进民生福

祉;不断思考研究中国医药发展的出路和未来,进一步整合配置创新资源,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、聚焦协同创新,推动激励政策的有效实施,保障我国医药创新产业高质量、可持续发展

近期,上海、广州以及北京市先后出台了医院用药、临床试验等方面的改革意见,特别是中央办公厅、国务院办公厅1月印发《浦东新区综合改革试点实施方案(2023-2027)》,明确提出坚持解放思想,守正创新,着力破解深层次体制机制障碍,增强发展的动力和活力;提出坚持开放合作、先行先试,建立与国际通行规则相互衔接的开放型经济新体制;特别明确提出“建立生物医药协同创新机制,推动医疗机构、高校、科研院所加强临床科研合作,依照有关规定允许生物医药新产品参照国际同类药品定价,支持创新药和医疗器械产业发展”。这些突破性论述为2024年的改革发展指明了方向,更为未来医药创新相关政策完善奠定了基础。我们将紧紧抓住这一契机,开展系统性和活动,推动相关政策尽快落地并从试点转化为全国实施,推动我国医保支付、药品审评和医药用药制度进一步完善。

(一) 继续开展医药政策和行业战略专题研究,积极探索推动完善医药创新相关政策路径和方案。

一是在北京市卫健委委托下,开展“北京市卫健委研究型病房动态评估(2024年度)”工作,动态分析研究型医院建设成效对产业发展影响,细化提升研究型病房的科研地位、加强产业创新与临床需求相结合的政策建议,助力提升围绕临床需求的原始创新能力,全力构建临床研究机构和创新医药产业的协作平台。

二是开展“探索以病人支付价和医保支付价为基础的创新支付体系研究”,提升源头创新的支付保障力度。

为解决高值源头创新产品医保谈判准入难题,系统研究国际药品价格管理中病人支付价和医保支付价的相关做法及经验,探索构建适于中国医保支付价与病人支付价相结合的创新支付模式,以促进高值创新药品的可及性和国际竞争力,同时保障医保基金的安全和激励企业持续创新的动力。

三是开展支持生物医药创新产业政策在地方先行先试制度研究,以激活市场和引导资本投入,促进产业向好发展。

结合地方产业发展现状,通过实地调研深入了解地方支持创新产业发展的政策实施效果,包括对产品研发、注册上市及后期商业化等支持。从适配政策供给与创新需求的角度,分析创新产业发展的薄弱环节,以此提出进一步优化区域产业竞争力的政策建议,为贯彻落实国家创新战略奠定可行性基础。

四是探索以已发表学术研究论文为基础,对不同领域优秀药物研发、临床试验及科技转化学术成果进行多维度综合评价,加强转化医学和成果转化,推动创新能力和水平的提升。

通过设立科学、客观的评价指标,借助已有学术文章,从不同维度评价科研人员学术贡献,尤其针对中青年科学家和科研人员在科学研究中发挥的重要作用,以期发掘和激励在医药创新研发和转化工作中发挥中坚力量的后备人才。

(二) 推动相关政策的制定和优化,以监管国际化带动产业国际化,支持中国创新药械企业融入全球化市场。

一是关注医疗器械创新产业发展的问题,以提升我国医疗器械监管创新的质量和效率。《医疗器械管理法》首次被列入立法规划,具有重大意义,通过开展医疗器械立法的国际比较研究,借鉴发达国家的经验做法,以构建国际化、现代化的科学监管体系,为我国医疗器械产业的监管和创新发展提供坚实的法律保障和指引。

二是开展国家局与港澳药械协同监管制度研究,促进监管能力提升和产业发展。通过分析国家药监局

与港澳特区药械监管的特点和差异,特别是在香港特区药品监管体系构建的背景下,探索协调一致的药械监管措施,以促进和内地药械监管体系的协调发展和良性互动,提升监管能力和水平,推动内地和大湾区产业的合作与发展,并适应国际药械监管趋势。

三是设立“中国创新药械全球化布局及出海模式研究”课题,推动产业国际化进程。通过案例分析和对比研究,总结出不同出海模式的优缺点和适用条件,为中国药械企业选择出海模式提供策略建议。同时,为政府部门制定优化相关政策提供参考,以期与产业形成合力推进中国药械国际化发展。

(三) 持续发挥产业与政府的纽带作用,加强与相关部门的沟通与合作,推进企业参与重大立法制度修订、政策制定及实施过程。

持续关注《医疗保障法》《医疗器械管理法》的立法进程,及时召开专题座谈会倾听产业发展动向,并向相关政府部门反映行业关切,促进立法完善;继续跟进《药品管理法实施条例》《中药品种保护条例》的修订及配套规章制度的制修订工作;持续关注医保准入和支付改革工作,对关键文件积极主动征求会员单位及专业委员会的建议,形成行业意见并反馈至相关部门。

紧扣产业发展,跟踪评估“中国医药企业创新能力指数”,从投入、过程、成果和回报等多个维度对新兴生物制药企业的创新能力和可持续性进行评价,以便及时发现薄弱环节,为政策制定提供支持,促进产业创新发展。

三、立足国内国际双循环相互促进的新发展格局,创造国际竞争优势,进一步提升中国在国际医药创新领域的话语权

(一) 积极践行“一带一路”倡议,加强与上合组织和“一带一路”沿线国家医药产业合作交流。

我会计划2024年组织医药企业高级别代表团出

访中亚、中东相关国家，考察当地医药产业投资环境，与医药卫生监管部门、医药行业协会、医药投资人及相关基金公司会谈，为助力中国医药企业“出海”，深化全球医药卫生合作，提升“一带一路”沿线国家卫生健康保障水平和人民福祉贡献力量。

此外，2024年中国将接棒担任上海合作组织轮值主席国，我会将以此为契机，协助成都申请主办“第三届上海合作组织医药合作发展大会”，发布“中国药械推荐名单”等，加快中国优质的医药创新药械产品进入上合组织国家，共同促进上合组织国家医药产业合作高质量发展，开创医药产业创新合作共赢新局面。

(二) 持续按照IFPMA秘书处和国家药监局ICH工作办公室要求，推荐业内本土权威专家到国际平台参与ICH指导原则的制修订工作，参与国际规则制定，发表中国观点；同时，配合国家药监局等相关监管部门做好ICH相关指导原则在中国转化实施工作，组织开展相关指导原则的解读及培训，稳步推进中国制药行业标准与国际接轨。

(三) 继续维护、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，寻求合作契合点，开展更多有利于我国医药创新产业发展的活动。并通过参与更多国际会议和交流活动，充分展现中国药监改革及中国医药产业创新成就。

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

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

我会将继续与国内外各相关机构鼎力合作，办好

一年一度的中国医药创新与投资大会、中国罕见病大会等品牌性活动，聚焦医药创新关键环节，搭建服务创新全链条各方的合作平台，为推动我国药械产业高质量发展贡献力量。

五、推动分支机构换届工作有序进行，不断汇聚高端资源要素，为促进整个药械产业跨界交流和创新探索新思路、开拓新路径、提供新方法

根据分支机构整体工作计划，2024年我会13个专业委员会拟创办多项业务活动并召开相关工作会议，全方位推动医疗健康产业创新、可持续、高质量发展。

(一) 开展主题丰富形式多样的业务交流活动，为医药产业各创新主体提供更多价值服务。

2024年上半年，医药数字化及创新疗法、创新医疗器械和医药创新投资专业委员会拟共同创办中国药械产业数字化创新高峰论坛。论坛将以“信息技术和金融服务与药械产业跨界融合创新”为主题，充分依托我会在人工智能和医疗器械领域资源优势，深度聚焦药械产业创新政策、创新技术研发、现代信息技术应用、投资趋势及经验分享等主题，搭建权威、专业、多维度的沟通合作平台，以撬动数字技术、金融资本和药械产业间跨界合作、融合发展。

结合产业热点话题和需求，继续办好中国糖尿病和代谢性疾病药物器械研发创新大会、中国生物医药与器械创新投资人论坛、中国医药创新政策论坛、紫金医药合规论坛、脑科学与脑神经医药创新论坛、心血管临床试验培训等专业领域活动，为推动我国药械产业高质量发展持续发声。

(二) 充分发挥高端资源集聚优势，为社会界提供专业的药械产业资讯和信息服务。

2024年，抗肿瘤药物临床研究、医药创新投资专业委员会将调研访谈顶级机构和专家，联合国际权威

媒体和咨询机构适时发布《2023年度中国抗肿瘤新药临床研究评述》和药械产业投资研究报告,为我国药械产业研发及投资活动提供参考。

(三) 做深做实换届保障工作,继续发挥专业委员会行业领袖和头部企业聚集效应,精准聚焦产业核心需求,解决实际问题。

根据我会分支机构2024年整体工作安排,医药创新投资、抗肿瘤药物临床研究和医药企业合规3个专业委员会拟于2024年完成换届工作。此外,我会还将研究发起设立CGT领域专业委员会的可能。

此外,我会相关分支机构还将推动临床急需药品临床研究和上市后临床试验服务、生物样本活库标准化建设等项目落地实施。

六、加深与地方政府及相关机构务实合作,为推动我国医药产业创新生态环境建设、加速构建中国式现代化生物医药创新集群发挥智囊智库作用

我会将持续发挥政府与产业之间的纽带作用,精准挖掘国家、政府有关部门、产业、科研、人才、孵化转化、资本市场等产业上下游各方需求,整合并合理配置高端资源要素,继续深化与地方政府、产业园区和相关机构的合作。助力其实现落户一批现代化创新主体、落地一批顶层制度及配套政策、融入一批高学历人才、引入一批专业性资金,孕育一批总部设在中国的跨国制药企业、产出一批中国原创惠及全球患者的创新产品、打造一批世界一流的高科技园区。

二十大报告提出深入实施“科教兴国战略”“人才强国战略”“创新驱动发展战略”,强调要“健全社会保障体系”“积极发展商业医疗保险”“深化医药卫生体制改革,促进医保、医疗、医药协同发展和治理”。生物医药产业作为国家重要战略性新兴产业,是关系人民健康和经济社会发展的重要支撑。在党的二十大精神的指引下,中国药促会将积极践行“创新驱动发展”等战略要求,继续围绕推动生物医药产业高质量发展的

主题,聚焦热点、痛点、堵点问题开展医药政策研究,加强国际交流与合作,做好政府与产业的桥梁,促进产学研医用全链条深度融合。诚邀各位一道,为我国生物医药产业创新升级,为提升群众健康获得感聚合合力、添动力、增活力。

以上报告,请理事会审议。

2022~2023 Annual Work Report & 2024 Work Proposal for China Pharmaceutical Innovation and Research Development Association

The Fifth Meeting of 11th Board of Directors, February 22, 2024

Dear All Directors,

General Secretary Xi Jinping stressed repeatedly that the biopharmaceutical industry is a strategic emerging industry that is of vital importance to the national economy, people's livelihood, and national security, so we should strengthen the construction of basic research and scientific and technological innovation capabilities to firmly grasp the lifeline of the biopharmaceutical industry development in our own hands. Guided by China's "innovation-driven" development strategy and other policies, the nation's biopharmaceutical industry has achieved remarkable results after more than a decade of development, such as continuously improving research and innovation capabilities and constantly expanding market size. However, there are still significant challenges in terms of original innovation, achievement transformation, etc.; due to geopolitics, global economic recession, as well as imperfect market systems such as domestic medical insurance access and hospital drug use, the investment in biopharmaceutical innovation has significantly decreased, severely affecting the development of some R&D-oriented innovative enterprises. As an association that promotes the high-quality development of the biopharmaceutical industry, PhIRDA has fully implemented the spirit of the 20th National Congress of the Communist Party of China (CPC), always paid close attention to national policy dynamics, deeply understood the needs of industrial development, and solidly carried out diverse and rich work, so as to contribute to China's social and economic development and people's health. The main work completed by PhIRDA in 2022~2023 is reported as follows:

Part I. Review of Major Work in 2022~2023

Since the Fourth Meeting of the 11th Board of Directors was held on September 22, 2022, led by Party building, oriented by problems, and with innovation as the core and services as the fundamental, PhIRDA has focused on the "stranglehold" issues of industry development, promoted research on pharmaceutical policies, built a multi-field and multi-form communication and cooperation platform in the industry, pushed forward the internationalization process of China's pharmaceutical industry, and made significant work achievements, which received widespread attention from society and were generally accepted in the industry.

I. Guided by Xi Jinping Thought on Socialism with Chinese Characteristics for a New Era, strengthen the Party spirit, seek development, make contributions, and steadily promote the high-quality development of all work of PhIRDA

In the past year, under the correct leadership of the superior Party committee, the Party branch of PhIRDA has adhered to the guidance of Xi Jinping Thought on Socialism with Chinese Characteristics for a New Era and conscientiously implemented the general requirements of Party building and the Party's organizational route in the new era. Led by the Party's political construction, relying on the standardized and normalized management of Party organizations, and ensuring further improvement of Party conduct and construction of a clean and honest government, the Party branch has carried out Party building work around the central idea of "strengthening the Party spirit, seeking development, and making contributions" in a serious and orderly manner. During the reporting period, the Party branch has actively developed 2

probationary Party members, increasing the total number of Party members to 12. From April to August 2023, the Party branch actively conducted the thematic education of “learning and implementing Xi Jinping Thought on Socialism with Chinese Characteristics for a New Era” and fully fulfilled the general requirements of the central thematic education of “learning thoughts, strengthening the Party spirit, emphasizing practices, and making new achievements”. Through theoretical learning, survey and research, and other learning practices, carrying out thematic education activities has become an important means to promote all work of PhIRDA. In addition, in strict accordance with the work deployment “I do practical things for the people”, PhIRDA has actively explored in improving the patient access to medicines, industrial innovation, and healthy development for the purpose of serving the industry and the people.

II. Give full play to the role of a high-end think tank, actively carry out monographic studies on pharmaceutical policies and strategies, submit suggestions and measures to multiple central ministries and commissions, and offer advice and suggestions for China’s reform of medical and healthcare systems, pharmaceutical technology development, improvement of pharmaceutical policies, and industrial development

(I) For the imbalance between the approval and supply of new anti-COVID-19 drugs in the prevention and control of COVID-19, PhIRDA organized experts, scholars and industry representatives to hold a symposium and reach a consensus, formed and submitted a proposal report entitled *Give Full Play to the Value of Pharmaceutical Innovation to Assist in the Prevention and Control of COVID-19* to the Central Committee for Deepening Overall Reform, and send a copy to six ministerial-level departments, including the National Development and Reform Commission (NDRC), the Ministry of Industry and Information Technology (MIIT), the Ministry of Science and Technology (MoST), the National Health Commission (NHC), the National Healthcare Security Administration (NHSA), and the National Medical Products Administration (NMPA).

(II) Focused on promoting the high-quality development of the industry through pharmaceutical innovation policies, and completed multiple research topics commissioned by national government departments based on investigation and research:

First, completed the *Report of Status Quo, Problems, and Suggestions on Development Strategies of China’s Pharmaceutical Industry and Research on China’s Top Ten Diseases and Their Medication Information* commissioned by the MoST; the monographic study *Report of Making China’s Pharmaceutical Industry Stronger, Better, and Bigger, Promoting the High-Quality Development of the Bioeconomy and Suggestions on Advancing the Building of a Pharmaceutical Modern System* entrusted by the Central Committee of Chinese Peasants and Workers Democratic Party; the monographic study work, such as *Report of Bottlenecks of Technologies in China’s Pharmaceutical Industry and Tackling Strategies* surveyed by the NDRC as well as the mid-term evaluation of the 14th Five-year Plan for Bioeconomy Development.

Second, for the continuous deepening of the reform of the medical product administration system, submitted feedbacks, such as *the 2023 Work Plan for Drug Supervision, the 2024 Work Plan for Drug Supervision, the Support Policy for Innovative Medical Device Industry, and the Legislation of the Medical Device Management Law*, to the NMPA.

(III) Paid continuous attention to the issue of medication security for special populations, summarized the reform achievements in relevant fields, and promoted and publicized legislation on rare diseases as well as establishment and optimization of systems related to children’s medicines, in order to establish a sound legal and institutional system that incentivizes rare diseases, research and supply of children’s medicines, patient diagnosis and treatment, reimbursement and payment to meet the medication needs of rare disease patients and children from multiple dimensions.

III. Have an insight into common industrial issues,

conduct high-quality project researches, promote optimization of the policy system and improvement of the pharmaceutical innovation environment

(I) Focused on the deep integration of the entire industry chain of “enterprises, higher education institutions, research institutions, and medical institutions”, actively undertake the projects commissioned by the government, and provide support for creating and constructing a favorable policy and market environment for the transformation of pharmaceutical innovation technology achievements

First, completed with high quality the project “A Comparative Study of R&D and Transformation Capability of Innovative Drugs in China and Abroad and Frontiers” commissioned by the Major Science and Technology Project Department of MoST, focused on promoting a breakthrough in key core technologies and transformation of achievements, put stress on sorting out the advantageous technologies of China’s key innovative drug research and development units (including colleges and universities, research institutes, and enterprises), and conducted a quantitative analysis of the development level of various technologies and the gap with foreign countries. By conducting surveys on the advantageous technologies of members and organizing a “Symposium for Young Scientists in Disruptive Technology Enterprises on Innovative Drug Research and Development”, comprehensively understood and analyzed the problems and challenges in original innovation, achievement transformation, talent scale and quality, and other aspects of China’s colleges, universities and research institutes, and proposed policy recommendations, providing reference for promoting pharmaceutical innovation transformation and high-quality industrial development.

Second, entrusted by Beijing Municipal Health Commission (BHC), carried out “Dynamic Assessment of the First Demonstration Units for Research-oriented Ward Construction in Beijing”, conducted in-depth research and comprehensive analysis of the achievements made by the first batch of 10 demonstration units since their construction in 2020, and formed a final evaluation

report and policy recommendations. Some policy recommendations, such as promoting researchers to initiate clinical researches, strengthening construction of a clinical research consortium consisting of hospitals, research institutions and enterprises for specialized diseases and specialties, and accelerating the application of innovative achievements in hospitals, have been adopted by relevant departments and issued as important documents such as *the Notice on Several Measures to Further Improve the clinical research Level in Beijing*; continuously carried out the dynamic evaluation of the construction of the second and third batches of research-oriented wards to promote construction through evaluation and improve the clinical research level of medical and health institutions as well as industrial development.

(II) Conduct independent research on pain points and bottlenecks in industry development, in the hope of overcoming the “stranglehold” problems and make up for the shortcomings in development

First, focused on the continuously optimizing renewal and adjustment rules for the National Drug Reimbursement List (NDRL), and conducted research on “Medical Insurance Access and Innovative Payment for Innovative Drugs”, laying the foundation for the accumulation of evidence throughout the entire lifecycle of innovative drugs as well as sustainable development.

Second, conducted research on “Innovative Drugs Payment Security System with Chinese Characteristics”, and put forward proposals from the top design of system construction, realization of innovative drug value, basic medical insurance access system, multi-level security system, and diversified innovative payment.

Third, co-conducted research on “Consensus on Methodology for Reference Drug Selection”, and formed a consensus by combining the operating standards for reference drug selection with practices to assist in an overall improvement of the level of health technology evaluation and evidence-based decision-making evidence.

Fourth, focused on the management system and mechanism of device evaluation, as well as the rational allocation of resources, conducted research on “The Reform of China’s Innovative Device Evaluation System”, and explored and promoted the modernization of China’s regulatory system and capability to assist in an innovation path of high-quality and independent development of the medical device industry.

Fifth, carried out “Research on Marketing Authorization Holder (MAH) System” to further clarify the key cruxes that affect the efficient use of overall innovation resources and constrain the internationalization process of Chinese pharmaceutical enterprises in the implementation of the MAH system and promote the better and more stable implementation of the MAH system in China.

Sixth, conducted research on “Pathways for the Going Global of China’s Innovative Drugs”, focused on ASEAN countries with a relatively high integration level and considerable economic development potential, studied and promoted “the consensus on the technological path and standards for drug administration and registration”, promoted the establishment of bilateral/multilateral agreements with ASEAN countries, and gradually achieved the sharing and mutual recognition of clinical trial data as well as review, examination, and testing standards and results, in order to promote the going global of China-made innovative drugs to integrate and link with the strategies of relevant national departments, push forward the issuance of policies conducive for innovative drugs to go global, and accelerate the internationalization of China’s pharmaceutical innovative products.

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

(I) Regarding *the Exposure Draft Revision of Implementation Regulations of the Drug Administration*

Law and Draft Revision of Regulations on Protection of Traditional Chinese Medicines, PhIRDA has actively solicited opinions from its members and provided feedback at the revision discussion meeting held by the NMPA.

(II) Regarding regulatory documents such as *the Measures for Scientific and Technological Ethics Review* and *the Notice on Strengthening Supervision of the Contract Manufacturing of Drug Marketing Authorization Holders*, PhIRDA has organized members to hold a discussion meeting, proposing practical suggestions of industrial guidance significance, such as avoiding duplicate review, shortening R&D cycles, fully protecting the legitimate rights and interests of enterprises, and encouraging provincial management institutions to carry out more flexible regional supervision. Many of these contents have been adopted by relevant departments and included in official documents for publication.

(III) Established a platform for communication between the government and enterprises and broadened the channel for cooperation between the government and enterprises. Assisted the MoST in conducting a series of researches on pharmaceutical development strategies; assisted the Center for Drug Evaluation (CDE) in conducting drug evaluation as well as a questionnaire survey on a ICH Guidelines training program; participated in the symposium on the exposure draft of *Guiding Opinions of the Pricing of COVID-19 Drugs* (Trial Implementation) upon invitation by NHSA, expressing the key concerns of the industry; organized members to participate in the CDE’s relevant topics and series of seminars, such as “Patient-Centered Drug R&D for Rare Diseases”; actively participated in various seminars and symposiums held by relevant government departments to provide industry opinions and suggestions, including the symposium of NPC & CPPCC deputies on multilevel security for rare diseases, the special seminar on advancing the building of a modern biopharmaceutical system, the research symposium on optimizing the evaluation process of innovative drugs/shortening the process of marketing innovative drugs, the seminar on analyzing the development situation of high-tech industries in the

first half of 2023, and the symposium on systems and mechanisms in the medical field.

V. Actively broaden channels for speak-out, strengthen communication and exchange, and expand the influence

First, held symposiums and communication meetings for enterprises and experts to address industry concerns, such as the symposium on building an ecological environment for sustainable development of China's pharmaceutical innovation.

Second, published academic articles and research reports according to the latest situation and research findings of industrial development, providing a scientific basis and reference for policy-making. For example, the research finding *Challenges to China's Pharmaceutical Innovation and Its Response* was included in the *Reform Internal Reference. The Review of the Approved Drugs for Rare Diseases in 2022 in China* was published in *China Pharmaceutical News*, and *the Analysis and Thinking on the Reform of Clinical Trial Data Supervision in China* was published in *the World Clinical Drug*.

VI. Deeply carry out international pharmaceutical exchanges and promote mutual exchanges and cooperation in the global pharmaceutical industry

(I) Actively participate in the formulation of international rules, organize experts to participate in the revision of the guidelines for drug regulatory standards, and promote the implementation and transformation of ICH Guidelines in China.

First, as a member of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA), PhIRDA has recommended 50 experts (including 14 Leads and 12 Alternates) to IFPMA to join 25 ICH Expert Working Groups (EWGs) since 2017. During the reporting period, the experts recommended by PhIRDA accounted for over 53% of the total number of IFPMA experts around the world.

Second, entrusted by the ICH Office of NMPA, PhIRDA solicited opinions from PhIRDA members and timely fed back industry opinions on 73 ICH Guidelines to promote the smooth implementation of ICH Guidelines in China. Entrusted by the CDE, PhIRDA actively recruited experts for ICH EWGs. During the reporting period, 107 experts recommended by PhIRDA have been included in 35 CDE ICH EWGs.

Third, PhIRDA invited multiple industry experts to conduct in-depth interpretation and sharing on topics, such as electronic application for drug registration as well as eCTD implementation strategy, quality risk management and drug lifecycle management, and standardization and reformation of clinical trials, from an industry perspective to help enterprises better adapt to the ICH Guidelines that have already been implemented and will soon be implemented.

Fourth, 2023 is the first year that the offline ICH Assembly was resumed after three years of COVID-19. Five IFPMA ICH experts recommended by PhIRDA attended meetings of ICH Guidelines, making positive contributions to accelerating the coordination and unity of regulatory rules, promoting international mutual recognition on regulation, and jointly promoting the development of the global pharmaceutical industry.

(II) Strengthen cooperation and exchanges in the pharmaceutical field with countries along the Belt and Road, and build a diversified communication platform with the healthcare regulatory authorities of SCO countries, contributing to improving the health security and well-being of people in all countries.

On the afternoon of March 29, 2023, PhIRDA held the International Pharmaceutical Innovation Forum of the 7th China BioMed Innovation and Investment Conference (CBIIC). Xu Jinghe, member of NMPA Leading Party's Members' Group and Deputy Commissioner of the NMPA, Shahlo Turdikulova, Deputy Minister of Ministry of Higher Education, Science and Innovation of the Republic of Uzbekistan, and Bobur Yahyoev, Consul General of the Embassy of the Republic of Uzbekistan in

China, attended the forum and delivered speeches.

On the afternoon of September 25, 2023, PhIRDA joined hands with the Good-Neighborliness, Friendship and Cooperation Commission of the Shanghai Cooperation Organization (GNFCC SCO), the Secretariat of the SCO, and the Embassy of the Republic of Kazakhstan in China to host the 2nd Shanghai Cooperation Organization Pharmaceutical Cooperation Development Conference. Nearly 30 high-level representatives and experts from the pharmaceutical, health, and technological innovation departments of 10 SCO countries, including Iran, Kazakhstan, Kyrgyzstan, Pakistan, Russia, Uzbekistan, Azerbaijan, Cambodia, Myanmar, and the United Arab Emirates, specially came to China to attend the conference. The participating countries jointly released the Suzhou Initiative, injecting a new strong impetus into building a closer SCO community with a shared future.

(III) Carry out exchanges with and visits to embassies and consulates, industry associations, and international organizations in various countries, share the achievements of China's drug regulation, promote international industrial exchanges, and promote win-win cooperation in the global pharmaceutical industry.

PhIRDA has always actively expanded new cooperation and developed new partners in international affairs, and maintained close contact with the embassies and consulates and related institutions of countries such as the United States, Canada, the United Kingdom, Australia, Japan, the Netherlands, Denmark, Spain, Switzerland, Finland, Italy, Belarus, Uzbekistan, Turkmenistan, Israel, Singapore, as well as international organizations such as IFPMA, APAC, and the Secretariat of the SCO; signed a memorandum of cooperation with the Asia-Pacific Bio-Med Exchange Centre INC (APBMEC) and the Hong Kong University of Science and Technology (HKUST) to jointly promote mutual exchanges and cooperation in the global pharmaceutical industry.

Upon invitation, PhIRDA attended international conferences such as the 11th Asia Regulatory Conference (ARC), the 2nd/3rd Asia Summit on Global Health

(ASGH), the 10th China Healthcare Summit, and the 2023 Asia Health and Life Sciences Innovation and Cooperation Summit (AHLICS), fully showcasing the achievements of China's pharmaceutical regulatory system and pharmaceutical innovation development and playing an important role in enhancing communication, understanding, and recognition between the world and China in the field of pharmaceutical innovation.

From February 26 to March 5, 2023, PhIRDA organized a high-level delegation of pharmaceutical enterprises to visit Hong Kong, China and Singapore. In addition to a visit to relevant government agencies and scientific research innovation departments, the delegation conducted an on-the-spot investigation of the local innovation industry park, and organized a pharmaceutical industry exchange meeting. This visit successfully promoted multiple members of PhIRDA to settle in the Hong Kong Science Park (HKSP) for the purpose of improving the transformation rate of innovative research achievements by utilizing the talent advantages of the HKSP and deeply integrating them into the national scientific and technological innovation strategy.

From November 28 to 30, 2023, PhIRDA organized a high-level delegation of pharmaceutical enterprises to visit Japan and co-hosted the Sino-Japan Pharmaceutical Industrial Meeting with the Japan Pharmaceutical Manufacturers Association (JPMA). In addition to a visit to the National Cancer Center (NCC) of Japan, the delegation conducted an on-the-spot investigation of Takeda Pharmaceuticals and Shonan iPark, making positive contributions to strengthening cooperation and exchange in China and Japan's pharmaceutical industry and helping China's innovative pharmaceutical enterprises "extend their footprint" to Japan and the Asia Pacific region.

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

(I) China BioMed Innovation and Investment Conference

In March and September 2023, PhIRDA co-hosted China BioMed Innovation and Investment Conference (CBIIC) twice with relevant institutions, with distinctive characteristics and ideas each. The 7th CBIIC set up a nearly 10,000-square meter special exhibition area “Clinical Research and Drug & Device Innovation” for the first time, and the 8th CBIIC resumed the parallel session of international exchange and cooperation for the first time after COVID-19; both CBIIC created multiple characteristic forums that are differential but complementary according to real-time hot topics, and continuously optimized and innovated in project screening, agenda planning, interactive experience, talent services, investment solicitation, and other aspects, helping all participants achieve information exchange, cooperation and mutual benefits, and sharing of achievements.

(II) 2022 China International Import Expo (CIIE) - 5th Hongqiao International Health Technology Innovation Forum

On November 6, 2022, PhIRDA joined hands with the International Health Exchange and Cooperation Center (IHECC) of the NHC to host the 5th Hongqiao International Health Technology Innovation Forum during the 2022 CIIE. At the forum themed with “Gathering Innovation and Breakthroughs and Building a Healthy Future”, leaders from the government, industry, clinical and research institutions, and investment community, as well as domestic and foreign expert representatives gathered together to discuss how to promote health technology innovation through international cooperation, deal with challenges in key diseases and public health fields, help build a Healthy China, and co-build global health and well-being.

(III) China Conference on Rare Diseases

In October 2022 and October 2023, PhIRDA worked with China Alliance for Rare Diseases (CARD) to host China Conference on Rare Diseases (CCRD) twice in Beijing. Focusing on core topics such as basic research, diagnosis and treatment, security, and industrial development in the

field of rare diseases, CCRD showcased China’s cutting-edge hotspots and technological innovation capabilities in the field of rare diseases from multiple dimensions, helping China’s rare disease prevention and protection to take a new step forward.

(IV) Oncolytic Virus Drugs Clinical R&D Forum

On April 8, 2023, the Oncolytic Virus Drugs Clinical R&D Forum hosted by PhIRDA was held in Beijing, which focuses on the research of innovative drugs for oncolytic viruses. At the forum, experts, researchers, entrepreneurs, and service providers from the field of oncolytic viruses gathered together to interpret industry development trends from multiple perspectives through the latest clinical data and R&D progress, contributing to the clinical research, application and transformation of innovative drugs for oncolytic viruses.

(V) 2023 China International Biopharma Conference

From November 17 to 18, 2023, PhIRDA and Hainan Broadcasting Station (HMG) jointly hosted the 2023 China International Biopharma Conference (CIBC). Focusing on the pain points in all links of pharmaceutical innovation, such as the government, enterprises, higher education institutions, scientific research institutions, users and investors, CIBC set up China International Biopharmaceutical Innovation Summit Forum, Innovative Drug Access Policy Sharing Forum, Global Anti-tumor Drugs R&D Summit Forum, and Pharmaceutical and Medical Device Innovation R&D Roadshow. Experts and scholars from all parties were invited for discussions and exchanges, contributing to boosting transactions and project investments in the pharmaceutical industry, leading system integration and innovation in the pharmaceutical industry, creating a high-end business cooperation platform, and promoting the high-quality development of the pharmaceutical industry.

(VI) 2023 The First Pujiang Biopharmaceutical Original Innovation Forum

On December 2, 2023, the First Pujiang Biopharmaceutical Original Innovation Forum hosted by PhIRDA was held in Shanghai, which focuses on “activating the first kilometer of original innovation”. Upon invitation, academicians and scientists from domestic and foreign top universities and research institutes, leading experts in clinical research, policy makers, partners of top venture capital institutions, and leaders of innovative enterprises gathered together to explore the key points and paths of original innovation from multiple dimensions, such as scientific discovery, scientific transformation, investment incubation, enterprise empowerment, and policy guidance, and discuss how to overcome the “involution” dilemma in the industry and cultivate and stimulate innovation momentum for industrial growth.

VIII. Continuously bring together high-end resource elements, promote the orderly progress of work at branches, and explore the establishment of themed, normalized, and branded characteristic activity platforms, contributing new forces to the high-quality and sustainable development of China’s pharmaceutical industry

During the reporting period, PhIRDA has officially established Innovative Medical Devices Specialty Committee and Digital Medicine and Innovative Therapy Specialty Committee, and completed the change of term for 11 specialty committees. Relying on the resource advantages of branch experts and committee members, PhIRDA has carried out a lot of effective work in seven areas, including pharmaceutical and medical device R&D, clinical research, industry regulation, policy research, investment and financing, pharmaceutical and medical device digitization, and compliance.

(I) Actively assist in the coordinated development of the entire pharmaceutical and medical device industry chain, and speak on behalf of pharmaceutical and medical device innovation subjects.

First, the specialty committees actively participated in the formulation and revision of government laws,

regulations, and guidelines, and formed and submitted multiple research findings and policy recommendations to relevant national departments. Some opinions and suggestions were adopted. In May 2023, experts from PhIRDA Clinical Research on Diabetes and Metabolic Disease Drugs Specialty Committee completed the draft proposals for *Technical Guidelines for Research and Development of Non-insulin Drugs for Type 1 Diabetes* and *Guidelines for Evaluation of the Pharmacokinetics and Pharmacodynamics of Insulin by Clamp Test* and submitted them to the CDE.

Second, participated in the reform of the capital market system and help get through the path for the listing of Specialist Technology Companies. On December 7, 2022, PhIRDA Specialty Committees on Digital Medicine & Innovation Therapy and Pharmaceutical Innovation Investment organized market participants, such as the Hong Kong Exchanges and Clearing Limited (HKEX), to-be-listed enterprises, investment institutions, securities firms, law firms, and accounting firms, as well as relevant experts and scholars to exchange opinions and conduct in-depth discussions on the specific terms and design intentions of Chapter “18C” about listing rules on the HKEX, and formed and submitted a “Suggestion on Listing Rules of Specialist Technology Companies” to the HKEX. The relevant suggestions were reflected in the system released by the HKEX on March 24, 2023.

Third, focus on clinical needs and contribute to improving patient access to medicines and reducing enterprise R&D costs. On April 11, 2023, PhIRDA Clinical Research on Cranial Nerve Drugs Specialty Committee convened a clinical needs demonstration meeting, enabling experts to demonstrate the actual clinical treatment needs of relevant drugs, and wrote to the CDE to advise the accelerated introduction of innovator drugs of relevant drugs into the Chinese market. The relevant drugs have been exempted from permits for clinical introduction into China.

(II) Solidly carry out basic research and guide construction of a sustainable and benign ecological environment for pharmaceutical and medical device innovation.

PhIRDA Clinical Research on Oncology Drugs Specialty Committee regularly conducts comprehensive review of popular targets and their mechanisms of action as well as current R&D status in China. In June 2023, it released *the 2022 Review of Clinical Research on New Anti-tumor Drugs in China* to guide the scientific, rational, and orderly development of pharmaceutical R&D.

(III) Be concerned with the clinical needs of patients and collaborate with clinical institutions and industry entities to contribute to meeting the clinical medication needs of patients.

PhIRDA Clinical Research on Cranial Nerve Drugs Specialty Committee joined hands with PhIRDA's members, such as Beijing Tiantan Hospital, BeiGene, and CR Double-Crane, to carry out relevant clinical studies and post-market clinical trial services, contributing to meeting the clinical medication needs of patients.

(IV) Continuously strengthen the legal and compliance construction, dynamically improve industry standards, and call for the construction of a benign and compliant ecological environment for the development of the pharmaceutical and medical device industry.

According to the latest changes in relevant laws and regulations and international standards in the field of compliance, PhIRDA Ethics and Business Compliance Specialty Committee has revised and improved *the Code of Ethics for Pharmaceutical Enterprises of China Pharmaceutical Innovation and Research Development Association* (to be released in 2024), providing a basis for standardizing the practice of members and relevant personnel and promoting the healthy and orderly development of the pharmaceutical and medical device industry.

(V) Bring together experts from different professional fields to build a branded and professional academic activity platform for promoting cross-border exchanges and innovative development in the entire pharmaceutical industry.

1. China Pharmaceutical and Medical Devices R&D for Diabetes and Metabolic Diseases Innovation Conference

On April 14, 2023, China Pharmaceutical and Medical Devices R&D for Diabetes and Metabolic Diseases Innovation Conference, hosted by PhIRDA Clinical Research on Diabetes and Metabolic Disease Drugs Specialty Committee, was held in Wuxi. Based on the clinical needs of diabetes and metabolic diseases and focusing on high-incidence diseases, the conference set up special forums around diabetes, obesity, NASH, osteoporosis, gout, investment and cooperation, research design and method, capacity building and training, etc.

2. China Pharmaceutical Innovation Policy Forum

On July 21, 2023, the 2023 China Pharmaceutical Innovation Policy Forum, jointly hosted by PhIRDA Specialty Committees on Medicinal Policy, Clinical Trial Research, Ethics and Business Compliance, and Innovation R&D Services, was held in Beijing. Paying close attention to the weak links in pharmaceutical policies, industrial innovation, and high-quality development, the forum set up themed forums, such as innovative drug access practice and exploration, promoting original innovation by high-quality clinical studies, and improving the quality and efficiency of clinical trials by new technology. Focusing on topics such as basic research and scientific research transformation, clinical trial level improvement, and compliance system construction, the forum aimed to remove mechanism obstacles in supervision, market access, practical use and other fields, smoothen channels for the transformation of innovative achievements, and comprehensively stimulate the original innovation capability and vitality of China's innovation subjects.

3. China Bio-Pharmaceutical and Medical Devices Innovation Investors Forum

On July 27, 2023, the third China Bio-Pharmaceutical and Medical Devices Innovation Investors Forum, jointly hosted by PhIRDA Specialty Committees on Pharmaceutical Innovation Investment, Digital Medicine and Innovative Therapy, and Innovative Medical Devices, was successfully held in Shenzhen. Themed with "Cross-border Integration and Innovation of

Information Technology and Financial Services with the Pharmaceutical Industry”, the forum aimed to leverage the integrated and innovative development of financial capital, information technology, and the pharmaceutical industry to achieve win-win cooperation.

In addition, relevant branches of PhIRDA also hosted a variety of business activities, including Pharmaceutical Innovation and Development Forum, 2023 Clinical Research of Anti-tumor Innovative Drugs Forum, China Pharmaceutical Industry Regulatory and Compliance Summit, relevant sub-forums of CBIIC, and the Academic Exchange Conference on Clinical Research of Innovative Drugs in the Cardiovascular Field, assisting in the construction of an ecological environment for the pharmaceutical industry.

(VI) Make innovations in the modes of activities and carry out online business activities that are flexible in dissemination and have a wider audience, speaking out on behalf the entire chain of pharmaceutical innovation.

From October to December 2022, PhIRDA specialty committees on Ethics and Business Compliance and Drug R&D held live streaming activities themed with “Zijin Pharmaceutical Compliance Forum: Exploration of the Compliance of Pharmaceutical Enterprises and Mechanism of Accountability Exemption” and “Pharmaceutical Innovation: 2023 Outlook of Pharmaceutical Innovation in China”, and worked with relevant cooperation units and media to comprehensively publicize, report and rebroadcast the live streaming activities, continuously speaking out for the pharmaceutical industry while actively responding to the COVID-19 epidemic prevention and control policies.

IX. Fully leverage the advantages of industrial resources, establish close connection with relevant local departments and professional institutions, deepen business linkage with local governments and industrial parks, and jointly serve the overall reform, innovation, and development of China’s pharmaceutical industry

In recent years, PhIRDA has actively explored new models of cross-border cooperation and integrated development with local governments, industrial parks, and other parties, and conducted a lot of researches and basic work on how to revitalize the existing space for the development of the pharmaceutical industry and expand the incremental space. Since October 2022, PhIRDA has maintained close connection with relevant departments of local governments in Beijing, Shanghai, Shenzhen, Chengdu, Wenzhou, Jiangsu, Anhui, Shandong and other provinces and cities, providing intellectual support for building world-class high-tech parks and modern biopharmaceutical manufacturing clusters.

X. Comprehensively strengthen and enhance the ability and level of member service work, and enhance the “sense of gain” and cohesion of PhIRDA’s members

(I) Continuously improve construction of the membership system and fully stimulate internal vitality.

Members are an important component of PhIRDA’s system. While continuously enhancing the cohesion of members and improving the quality of member services, PhIRDA is also actively exploring more outstanding innovative entities and optimizing the membership structure. By the voting of the Communication Board of Directors, during the reporting period, PhIRDA has recruited a total of 21 new members. As of now, PhIRDA has had a total of 183 members of various types, covering the entire industry chain such as pharmaceutical enterprises, device enterprises, research institutes, clinical research institutions, innovation service institutions, and pharmaceutical investment institutions. In addition, the membership applications of three companies will be submitted at this meeting for all board directors to deliberation. For details, please refer to the “Proposal for Developing Members”.

(II) Actively interlock resources from all parties, enrich the forms of member activities, and jointly seek a new future for industrial development.

In order to gain a deeper understanding of the development trends of its members, strengthen horizontal linkage among members, and promote deep industrial exchanges and cooperation, PhIRDA has continuously enhanced the transmission of industry information through member activities such as holding online and offline symposiums, conducting researches and visits to members, and organizing exchanges and visits between members, for the purpose of building platforms and creating possibilities for cooperation among members. In 2023, PhIRDA convened a regional member exchange seminar in Shanghai, Suzhou, Chengdu, Shenzhen, and other places, allowing leaders of PhIRDA and industry experts to lead a visit and survey to 16 members.

(III) Actively provide member publicity services and build a dynamic brand promotion platform for members.

Starting from 2023, PhIRDA has regularly collected major achievements and important matters (assessment and approval results, R&D progresses, investment and financing, strategic cooperation, etc.) from members, and provided daily publicity services for members in the form of a collection of member developments (46 issues have been released in 2023); paid close attention to the development trends of members and made a special coverage on important milestones. The above contents are released through the official account, website and other self-owned platforms of PhIRDA, as well as cooperative high-quality media channels to fully demonstrate the development style and feature of high-quality innovation subjects in China.

(IV) Give full play to the functions and roles of an industry association, further enhance the contents and capabilities of member services, and grow together with members.

Given that the national and local governments require professional recommendation or certification documents from industry associations for enterprises to apply for relevant projects and awards, upon the application of members and the prudent evaluation and argumentation of all parties, PhIRDA has, in accordance with the

principle of being responsible for the government and enterprises, issued certification documents such as national Specialized, Elaborative, Characteristic, and Emerging “Little Giant”, recommendation on initial price for COVID-19 drugs, and green factory project, to help members to apply for honors and protect the legitimate rights and interests of members.

XI. Fullfill the social responsibility in the pharmaceutical industry and fully promote the aid for Tibet

From August 9 to 12, 2023, the activity “Healthier Tibetans: 2023 Academicians and Experts Free Diagnosis”, co-hosted by Tibet Development Fund (TDF), Health Commission of the Tibet Autonomous Region, and Lhasa Municipal People’s Government and co-organized by PhIRDA, was held in Lhasa. Many members actively responded and participated, such as Qilu Pharmaceutical, Simcere Pharmaceutical, Youcare Pharmaceutical, Shanghai Pharmaceuticals, and Fosun Pharma. A total of 217 experts and volunteers, including academicians from relevant fields, experts from domestic well-known tertiary hospitals as well as practitioners in orthopedics, gynecology, traditional Chinese medicine and other fields, in 21 provinces and 39 cities across China participated in the activity. They were in six groups to provide diagnosis and treatment services in Chengguan District, Duilong District, Dazi District, Qushui County, Linzhou County and other areas, helping the Tibetan people to raise their health management awareness and effectively improve their health status and life quality. PhIRDA and relevant members were also highly recognized and praised by TDF Chairman Panchen Lama.

With the joint efforts and struggles of all colleagues, PhIRDA has become an important social force in promoting the high-quality development of the biopharmaceutical industry. I hereby would like to express my sincere thanks to all members and branch committee members for your trust, support, and assistance! In the future, we will continue to leverage the platform advantages of PhIRDA, adhere to the purpose

of establishing PhIRDA, and under the leadership of the Party, strive to improve the ecological environment for the pharmaceutical industry, promote the innovative development of the biopharmaceutical industry, and sharpen China's competitiveness in the global biopharmaceutical field. In the new year, PhIRDA will carry out work by focusing on the following areas:

Part II. Proposal for Key Work in 2024

I. Continue to strengthen construction of Party organizations, further enhance learning of theoretical knowledge, and provide strong organizational guarantee for building an influential industry association

In the new year, PhIRDA will continue to take the learning and implementation of Xi Jinping Thought on Socialism with Chinese Characteristics for a New Era as the main theme of all work, run it throughout all work, seriously study the spirit of the 20th National Congress of the CPC and the spirit of General Secretary Xi Jinping's important speeches, consolidate the theoretical foundation and cultivate a good work style; make full use of activities such as "Three Meetings and One Lecture" and "Theme Party Day" to effectively play the political leadership and fortress role of Party organizations, focus on improving the ability to master the political situation, overall planning ability, investigation and research ability, and ability to connect with the masses, and continuously enhance the people's livelihood and well-being sincerely from the perspective of an association; continuously ponder over and research the way out and future of China's pharmaceutical development, further integrate and allocate innovative resources, comprehensively promote the high-quality and innovative development of the industry, and untiringly strive to achieve the Second Centenary Goal and the Chinese Dream of great rejuvenation of the Chinese nation.

II. Focus on collaborative innovation, promote the effective implementation of incentive policies, and ensure the high-quality and sustainable development of China's pharmaceutical innovation industry

Recently, Shanghai, Guangzhou, and Beijing have successively issued reform opinions on hospital medication, clinical trials, and other aspects. In particular, the General Office of the CPC Central Committee and the General Office of the State Council issued the Implementation Plan for Pilot Comprehensive Reform of the Pudong New Area (2023-2027) in January, which clearly proposes to adhere to emancipation of the mind and innovation based on the right path, focus on breaking down deep-seated system and mechanism obstacles, and enhance the driving force and vitality of development; proposes to adhere to open cooperation and first try, and establish a new open economic system that is interconnected with international prevailing rules; particularly proposes to "establish a collaborative innovation mechanism for the biopharmaceutical industry, promote medical institutions, colleges and universities, and research institutes to strengthen clinical research cooperation, allow new biopharmaceutical products to be priced by referring to international similar drugs in accordance with relevant regulations, and support the development of innovative drug and medical device industries. These groundbreaking expositions have pointed out the direction for the reform and development in 2024, and laid the foundation for the improvement of future pharmaceutical innovation policies. We will seize this opportunity to carry out systematic researches and activities, promote the implementation of relevant policies and the promotion of pilot policies around the country as soon as possible, and boost the further improvement of China's medical insurance payment, drug evaluation, and medication systems.

(I) Continuously conduct monographic study on pharmaceutical policies and industry strategies, and actively explore the path and plan for improving the policies related to pharmaceutical innovation.

First, entrusted by the BHC, carry out "BHC Dynamic Assessment of Research-oriented Wards (2024)", conduct a dynamic analysis of the influence of research-oriented hospital construction on industrial development, refine the policy recommendations of elevating the research status of research-oriented wards and strengthening

the combination of industrial innovation with clinical needs, help enhance the original innovation ability around clinical needs, and make full efforts to build a collaborative platform for clinical research institutions and the innovative pharmaceutical industry.

Second, carry out “Research on an Innovative Payment system Based on Patient Payment Prices and Medical Insurance Payment Prices”, and enhance the payment security for original innovation.

In order to solve the problem of being difficult for high-value original innovation products to join in medical insurance, conduct systematic research on the relevant practices and experiences of patient payment prices and medical insurance payment prices in international drug price management, and explore the construction of an innovative payment model suitable for China’s medical insurance payment prices and patient payment prices, in order to promote the accessibility and international competitiveness of high-value innovative drugs, ensure the safety of medical insurance funds and motivate enterprises to continue innovation.

Third, carry out research on a local pilot system for policies supporting the biopharmaceutical innovation industry, in order to activate the market, guide capital investment, and promote positive development of the industry.

In combination with the current status of local industrial development, conduct field research to gain a deeper understanding of the implementation effects of local policies for supporting the development of innovative industries, including support for product R&D, registration and marketing, and later commercialization. From the perspective of adaptive policy supply and innovation demand, analyze the weak links in the development of innovative industries and thus propose policy recommendations for further optimizing regional industrial competitiveness and lay a feasible foundation for implementing the national innovation strategy.

Fourth, explore the multidimensional comprehensive

evaluation of excellent academic achievements on drug R&D, clinical trials, and scientific and technological transformation in different fields based on published academic research papers, strengthen translational medicine and achievement transformation, and promote improvement of the innovation capability and level.

By establishing scientific and objective evaluation indexes and utilizing the existing academic articles, evaluate the academic contributions of researchers from different dimensions, especially the important roles played by young and middle-aged scientists and researchers in scientific research, in order to discover and motivate reserve talents who play a backbone role in pharmaceutical innovation, R&D, and transformation.

(II) Promote the formulation and optimization of relevant policies, drive industrial internationalization through internationalized supervision, and support China’s innovative pharmaceutical and medical device enterprises to integrate into the global market.

First, pay attention to the development of the medical device innovation industry to improve the quality and efficiency of innovation in China’s medical device supervision. *The Law on the Management of Medical Devices* has been included in the program of legislation for the first time, which is of great significance. By conducting international comparative research on medical device legislation and drawing on the experiences and practices of developed countries, build an international and modern scientific supervision system to provide solid legal security and guidance for the supervision and innovative development of China’s medical device industry.

Second, carry out research on the collaborative supervision system between the NMPA and Hong Kong and Macao drug and medical device regulatory departments, and promote improvement of the regulatory capacity as well as industrial development. By analyzing the characteristics and differences between the NMPA and Hong Kong and Macao drug and medical device regulatory departments, especially in the context of

constructing a drug regulatory system in the Hong Kong Special Administrative Region, explore coordinated and consistent drug regulatory measures to promote the coordinated development and positive interaction with the drug regulatory system in the Chinese mainland, raise the regulatory capability and level, promote cooperation and development of industries in the Chinese mainland and the Greater Bay Area, and adapt to the international drug and medical device regulatory trend.

Third, set up the project “Research on the Global Layout and Going-Global Mode for China’s Innovative Drugs and Medical Devices” to promote the internationalization process of the industry. Through case analysis and comparative research, summarize the advantages, disadvantages, and applicable conditions of different going-global modes, and provide strategic suggestions for China’s pharmaceutical enterprises to choose appropriate going-global modes. At the same time, provide reference for government departments to formulate and optimize relevant policies, with an aim to form a joint force with the industry to promote the international development of China’s pharmaceutical and medical device industry.

(III) Continuously play the role of the industry and government as a link, strengthen communication and cooperation with relevant departments, and promote enterprises to participate in the revision of major legislative systems as well as formulation and implementation of policies.

Pay continuous attention to the legislative process of the Law on Healthcare Security and the Law on the Management of Medical Devices, timely convene special symposiums to listen to the development trends of the industry, reflect industry concerns to relevant government departments, and promote the perfection of legislation; continue to follow up on the revision of the Regulations for the Implementation of the Drug Administration Law and the Regulations on Protection of Traditional Chinese Medicines as well as the formulation and revision of supporting rules and regulations; pay continuous attention to the reform of medical insurance access and payment, actively seek suggestions from members and

specialty committees on key documents, and form and submit industry opinions to relevant departments.

Closely based on industrial development, track and evaluate the “Innovation Capability Index of China’s Pharmaceutical Enterprises”, assess the innovation capability and sustainability of emerging biopharmaceutical enterprises from multiple dimensions such as input, processes, results, and returns, in order to timely identify weak links, provide support for policy formulation, and promote industrial innovation and development.

III. Based on the new development pattern of domestic and international dual circulation and mutual promotion, create international competitive advantages, and further enhance China’s voice in the field of international pharmaceutical innovation

(I) Actively fulfill the Belt and Road Initiative(BRI), and strengthen cooperation and exchanges in the pharmaceutical industry with the SCO countries as well as countries along the BRI.

In 2024, PhIRDA plans to organize a high-level delegation of pharmaceutical enterprises to visit relevant countries in the Central Asia and the Middle East, investigate the local pharmaceutical industry investment environment, and conduct a talk with the medicine and health regulators, pharmaceutical industry associations, pharmaceutical investors and relevant fund firms, so as to promote China’s pharmaceutical enterprises to “go global”, deepen global cooperation on medicine and health, and improve the health security and people’s well-being in countries along the BRI.

Moreover, in 2024, China will assume the SCO rotating presidency. Taking this opportunity, PhIRDA will assist Chengdu in applying for hosting the “3rd Shanghai Cooperation Organization Pharmaceutical Cooperation Development Conference”, release the “List of Recommended Drugs and Devices in China”, to accelerate the access of China’s high-quality innovative pharmaceutical products to the SCO countries, jointly

promote the high-quality development of pharmaceutical industry cooperation among SCO countries, and create a new situation of win-win cooperation in the pharmaceutical industry innovation.

(II) Continuously recommend local authoritative experts in the industry to participate in the formulation and revision of ICH Guidelines, participate in the formulation of international rules and express opinions on behalf of China in accordance with the requirements of the Secretariat of the IFPMA and the ICH Office of the NMPA; cooperate with the NMPA and other regulators to complete the transformation and implementation of relevant ICH Guidelines in China, organize the interpretation and training on relevant guidelines, and steadily promote China's pharmaceutical industry standards to comply with international standards.

(III) Continue to maintain and expand cooperation and exchanges with embassies and consulates, industry associations, and social organizations of various countries in China, seek fitting cooperation points, and carry out more activities that are conducive to the development of China's pharmaceutical innovation industry. And by participating in more international conferences and exchanges, fully demonstrate the achievements made in China's pharmaceutical regulatory system and pharmaceutical industry innovation.

(IV) Further integrate and allocate resources to further help China's pharmaceutical enterprises improve their international competitiveness, help members to acquire more new drug R&D trends and overseas cooperation opportunities in the medicine and health field, and promote the deep integration of China's pharmaceutical industry with the international community in trade, investment, technology, and other fields.

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

PhIRDA will continue to cooperate with relevant institutions at home and abroad to hold annual brand

events such as CBIIC and CCRD, focus on key links in pharmaceutical innovation, and build a cooperation platform for all parties in the entire service innovation chain to promote the high-quality development of China's pharmaceutical and medical device industry.

V. Promote the orderly change of term for branches, continuously bring together high-end resource elements, and explore new ideas, paths, and methods for promoting cross-border exchanges and innovative development of the entire pharmaceutical and medical device industry

According to the overall work plan of branches, in 2024, a total of 13 specialty committees of PhIRDA will create multiple activities and hold relevant work meetings to comprehensively promote the innovative, sustainable and high-quality development of the healthcare industry.

(I) Carry out exchange activities with rich themes and diverse forms to provide more high-value services for various innovative entities in the pharmaceutical industry.

In the first half of 2024, PhIRDA Specialty Committees on Digital Medicine and Innovative Therapy, Innovative Medical Devices, and Pharmaceutical Innovation Investment plan to jointly establish China Digital Innovation Summit Forum for the Pharmaceutical and Medical Device Industry. Themed with "Cross-border Integration and Innovation of Information Technology and Financial Services with the Pharmaceutical Industry", the forum will, fully leverage the resource advantages of PhIRDA in the fields of artificial intelligence and medical devices, deeply focus on topics such as pharmaceutical industry innovation policies, innovative technology R&D, modern information technology application, and investment trend and experience sharing, and build an authoritative, professional, and multi-dimensional communication and cooperation platform to leverage cross-border cooperation and integrated development among digital technology, financial capital and the pharmaceutical and medical device industry.

In combination with the hot topics and needs of the

industry, PhIRDA will continue to hold professional activities well, such as China Pharmaceutical and Medical Devices R&D for Diabetes and Metabolic Diseases Innovation Conference, China Bio-Pharmaceutical and Medical Devices Innovation Investors Forum, China Pharmaceutical Innovation Policy Forum, Zijin Pharmaceutical Compliance Forum, Pharmaceutical Innovation Forum for Brain Science and Cranial Nerve, Clinical Trial Training for Cardiovascular Disease, and continue to speak out for promoting the high-quality development of China's pharmaceutical industry.

(II) Give full play to the agglomeration advantages of high-end resources and provide professional pharmaceutical and medical device industry information and services for all walks of life.

In 2024, PhIRDA Specialty Committees on Clinical Research of Oncology Drugs and Pharmaceutical Innovation Investment will conduct research and interview with top institutions and experts, and joint hands with international authoritative media and consulting agencies to timely release *the 2023 Review of Clinical Research on New Anti-tumor Drugs in China* and the investment research report for the pharmaceutical and medical device industry as reference for research and investment activities in China's pharmaceutical industry.

(III) Deepen and solidify the term change work, continue to play the industry leader role of specialty committees as well as the agglomeration effect of top enterprises, accurately focus on the core needs of the industry, and solve practical problems.

According to the overall work arrangement of the branches of PhIRDA in 2024, three Specialty Committees on Pharmaceutical Innovation Investment, Clinical Research of Oncology Drugs, and Ethics and Business Compliance plan to complete their term change in 2024. In addition, PhIRDA will also explore the possibility of initiating the establishment of a specialty committee in the field of CGT.

The relevant branches of PhIRDA will also promote the

implementation of projects such as clinical research on urgently needed drugs, post-market clinical trial services, and standardized construction of living biobanks.

VI. Deepen practical cooperation with local governments and relevant institutions, and play the role as a think tank in promoting construction of an ecological environment for China's pharmaceutical industry innovation and accelerating construction of a Chinese-style modern biopharmaceutical innovation cluster

PhIRDA will continue to play the role as a link between the government and the industry, accurately tap into the needs of the country, relevant government departments, industry, scientific research, talents, incubation and transformation, capital market and other upstream and downstream industries, integrate and reasonably allocate high-end resource elements, and continue to deepen cooperation with local governments, industrial parks, and relevant institutions. PhIRDA will assist them in settling down a group of modern innovation subjects, implementing a group of top-level systems and supporting policies, integrating a group of highly educated talents, introducing into a group of professional funds, nurturing a group of transnational pharmaceutical enterprises headquartered in China, producing a group of original innovative products in China that benefit global patients, and building a group of world-class high-tech parks.

The report of the 20th National Congress of the CPC proposed to deepen implementation of the "Strategy for Invigorating the China through Science and Education," "Workforce Development Strategy" and "Innovation-driven Development Strategy" and stressed the need to "improve the social security system," "actively develop commercial medical insurance", "further reform the medical and healthcare systems, and promote coordinated development and regulation of medical insurance, medical services, and pharmaceuticals". The biopharmaceutical industry, as an important strategic emerging industry in the country, is an important support for the people's health as well as economic and

social development. Under the guidance of the spirit of the 20th National Congress of the CPC, PhIRDA will actively fulfill the requirements of strategies such as “Innovation-driven Development Strategy”, continue to conduct research on pharmaceutical policies by focusing on hot topics, pain points, and bottlenecks for the purpose of promoting high-quality development of the biopharmaceutical industry, strengthen international exchanges and cooperation, serve as a bridge between the government and the industry, and promote deep integration of the entire chain of enterprises, higher education institutions, scientific research institutions, hospitals and application. We sincerely invite everyone to join us to pool strength, gather momentum and boost vitality in promoting innovation and upgrading of China’s biopharmaceutical industry, and enhancing the sense of health gain for the people.

This report is hereby submitted to the Board of Directors for review.



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