PhIRDA
中国药促会

中国医药创新促进会会刊

CHINA PHARMACEUTICAL INNOVATION AND RESEARCH DEVELOPMENT ASSOCIATION JOURNAL

（2025年6月编制）

创　新 | 产业化 | 国际化

INNOVATION | INDUSTRIALIZATION | INTERNATIONALIZATION

会长寄语

破局立新，共赴未来

会长

张抒扬

2024是生物医药产业格局加速升级的一年，也是生物医药产业破局向新的一年，在创新驱动发展战略指引下，“创新药”首次写进政府工作报告，“全链条”支持创新药发展政策不断释放发展红利，税收优惠、资金支持、新药专项、审评审批改革等措施相继出台，我国生物医药产业发展步入前所未有的“快车道”，在研新药数量跃居全球第二，国产创新药市场规模突破1000亿元，全球化合作进一步加速。这些突破性进展印证着我国医药创新体系已深度融入全球产业链，正以“源头创新+国际品质”重塑全球医药创新版图。作为产业的推动者，中国药促会始终与行业同仁同心同向，这一年在政策研究、国际交流、品牌建设等多个维度开展了大量卓有成效的工作，用实际行动印证着“政产学研用”协同创新的平台价值，为中国医药创新注入强劲动能。

展望2025这个“十四五”规划决胜之年，我将与药促会的会员一道继续化信任为责任，变压力为动力，紧握使命之舵，扎实做好行业引领和服务工作。进一步加强与政府部门的沟通交流，持续分析和研究行业热点、难点问题，为完善创新药和医疗器械的相关政策法规建言献策；积极搭建产学研用医合作平台，促进高校、科研机构、企业和资本之间的深度合作，加速科技成果转化，实现创新资源的优化配置和高效利用；加强与国际医药组织、企业、科研机构的交流合作，积极参与国际规则制定，提升中国在全球医药领域的话语权和影响力，为中国医药产品走向国际市场创造有利条件；开展更加广泛的合作与交流，锚定临床急需和未被满足的重大需求，推动更多高品质药物上市，让有温度的科技创新驱动人类更加美好、健康的未来！

志合越山海，聚力共前行。站在医药创新由“并跑”向“领跑”跃迁的历史节点，让我们以攀登者的勇气拥抱变革，以实干家的智慧破解困局，共同书写属于中国医药创新者的时代华章，携手缔造更多守护生命的中国答案！

MESSAGE FROM CHAIRMAN OF PhIRDA

Break Boundaries for Innovation, Forge the Future Together

The year 2024 marks the year of expedited upgrading of the industrial landscape of the biopharmaceutical industry, as well as the year of a breakthrough to a new era for the biopharmaceutical industry. Guided by the innovation-driven development strategy, the term "Innovative Drug" was, for the first time, included in the government work report. The "full chain" policy of supporting the development of innovative drugs has continuously unleashed benefits for development. Measures including tax incentives, financial support, new drug projects, and reform of the review and approval system have been successively introduced. The development of the biopharmaceutical industry in China has entered an unprecedented "fast lane", with the number of innovative drugs under research ranking second in the world, the market size of domestically produced innovative drugs exceeding RMB 100 billion, and further acceleration of global cooperation. These breakthroughs have demonstrated that China's pharmaceutical innovation system has been deeply integrated into the global industrial chain and is reshaping the global landscape of pharmaceutical innovation with "Original Innovation with International Quality". China Pharmaceutical Innovation and Research Development Association (PhIRDA), as a propeller of the industry, has been aligned with industry colleagues. This year, it has undertaken a great deal of fruitful work in multiple dimensions including policy research, international exchanges, and brand construction, etc., and has demonstrated with practical actions the value of the platform for collaborative innovation involving government, industry, academia, research institutes and application, thereby infusing robust momentum into pharmaceutical innovation in China.

Looking into 2025, the decisive year of the 14th Five-Year Plan, PhIRDA will continue to join efforts with its members to turn trust into responsibility, pressure into motivation, firmly hold the helm of mission, and steadfastly lead and serve the industry. PhIRDA will further intensify its communication with government authorities, continuously analyze and study industry hotspots and challenges, propose recommendations for improving policies and regulations related to innovative drugs and medical devices; proactively establish a platform for collaboration between industry, academia, research institutes and hospitals, promote in-depth cooperation between universities, research institutes, enterprises and capital, expedite the transformation of scientific and technological achievements, and enable the optimal allocation and efficient utilization of innovative resources. Furthermore, it will strengthen exchanges and cooperation with international pharmaceutical organizations, enterprises and research institutes, proactively participate in the drafting of international rules, making the voice of China heard in the global pharmaceutical industry, and create favorable conditions for Chinese pharmaceutical products to go global. Further efforts will be made to engage in more extensive cooperation and exchanges, anchor urgent and unmet clinical demands, facilitate the launch of more high-quality drugs, and enable technological innovation with a human touch to fuel an even better and healthier future for mankind!

Unite beyond borders, advance together forward. Standing at a historic point in the transition of pharmaceutical innovation from "running alongside" to "taking the lead", let's embrace the changes with the courage as climbers, crack the dilemma with the wisdom of pragmatists, and jointly compose an inspiring chapter of the era belonging to Chinese pharmaceutical innovators, and collaborate to create more Chinese solutions to safeguard lives!

CONTENTS 目录

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176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、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构架，并作为国际药品制造商协会联合会（IFPMA）的成员继续拓展国际交流渠道。

中国药促会工作内容主要包括：一是开展医药政策研究，为我国医改事业、完善药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

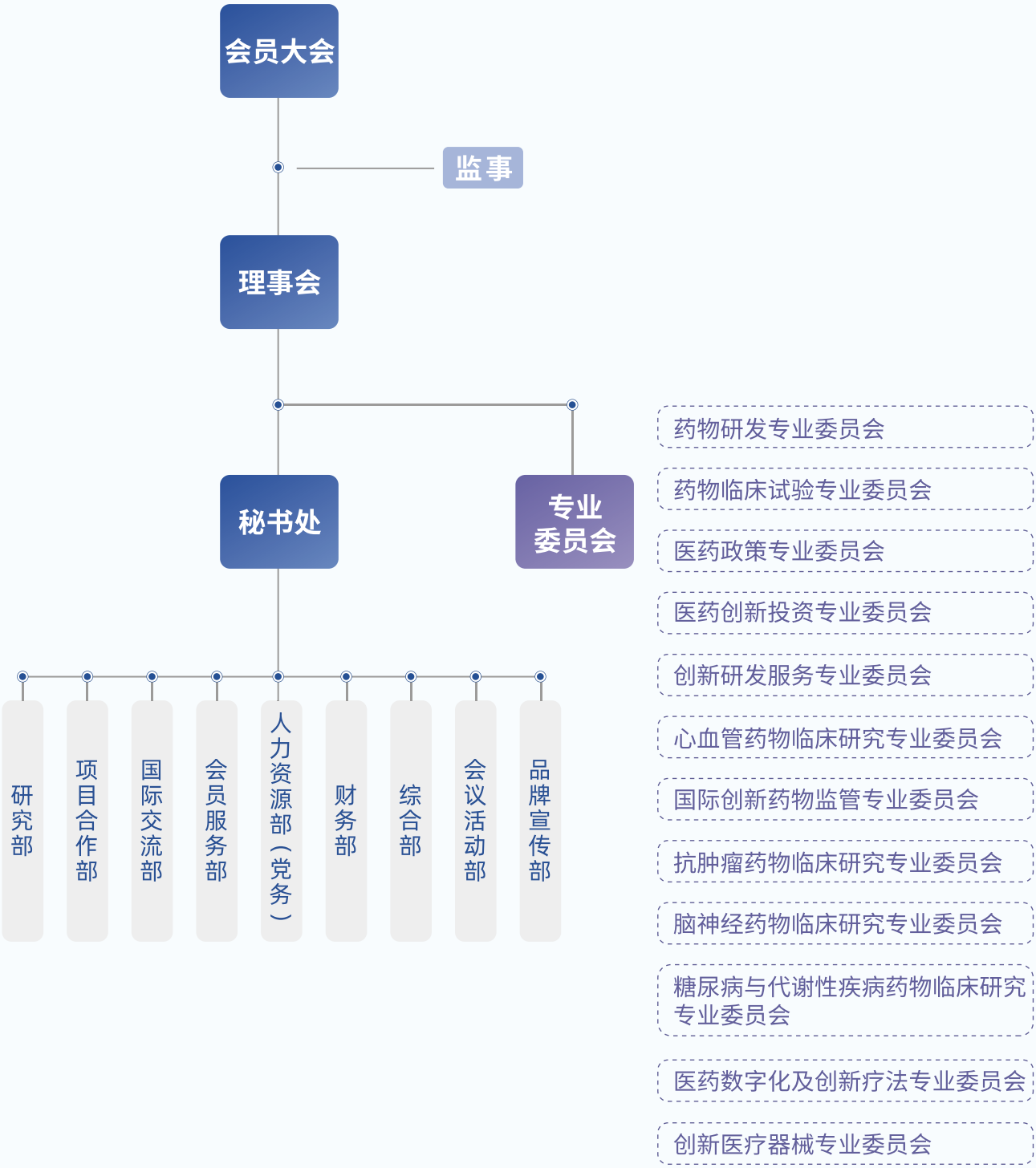
Founded in 1988, China Pharmaceutical Innovation and Research Development Association (PhIRDA), formerly named China Pharmaceutical Industry Research and Development Association, is registered as a non-profit 4A social organization by the Ministry of Civil Affairs of China at national level.

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 176 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, Clinical Research on Diabetes and Metabolic Diseases, 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.

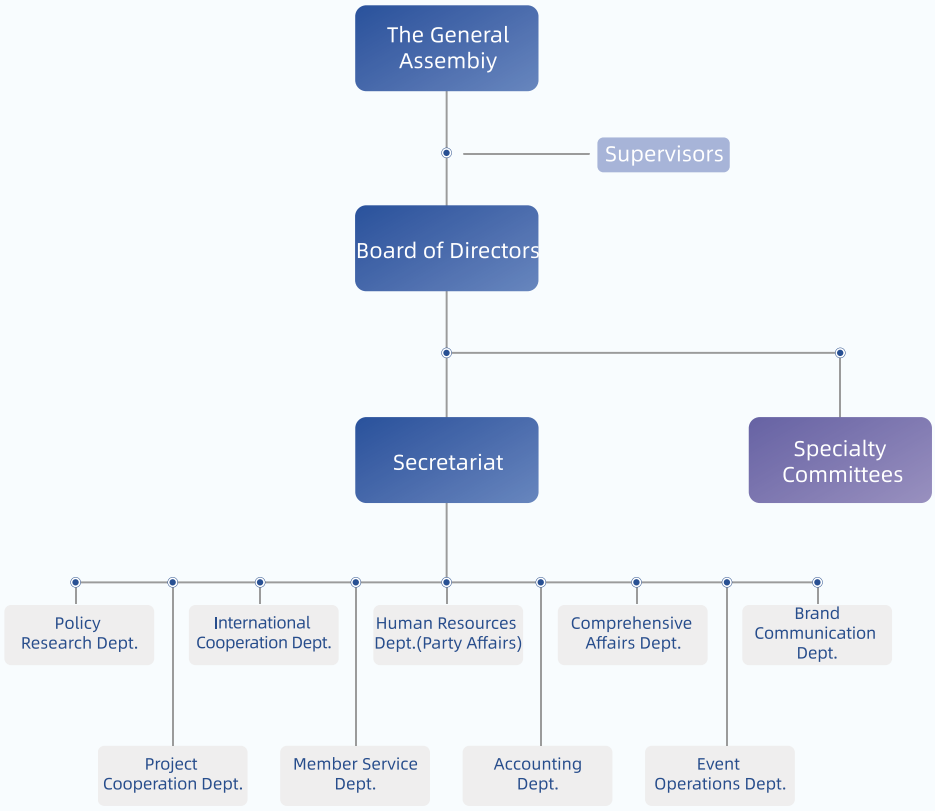
Major work of PhIRDA includes: first, to conduct policy researches, propose valuable suggestions on healthcare reform and the development of pharmaceutical industry; second, to promote communication and innovative development of our members and even the whole pharmaceutical industry through forums, press-conferences, 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


会员大会
监事
理事会
秘书处
专业委员会
研究部
项目合作部
国际交流部
会员服务部
人力资源部（党务）
财务部
综合部
会议活动部
品牌宣传部
药物研发专业委员会
药物临床试验专业委员会
医药政策专业委员会
医药创新投资专业委员会
创新研发服务专业委员会
心血管药物临床研究专业委员会
国际创新药物监管专业委员会
抗肿瘤药物临床研究专业委员会
脑神经药物临床研究专业委员会
糖尿病与代谢性疾病药物临床研究专业委员会
医药数字化及创新疗法专业委员会
创新医疗器械专业委员会

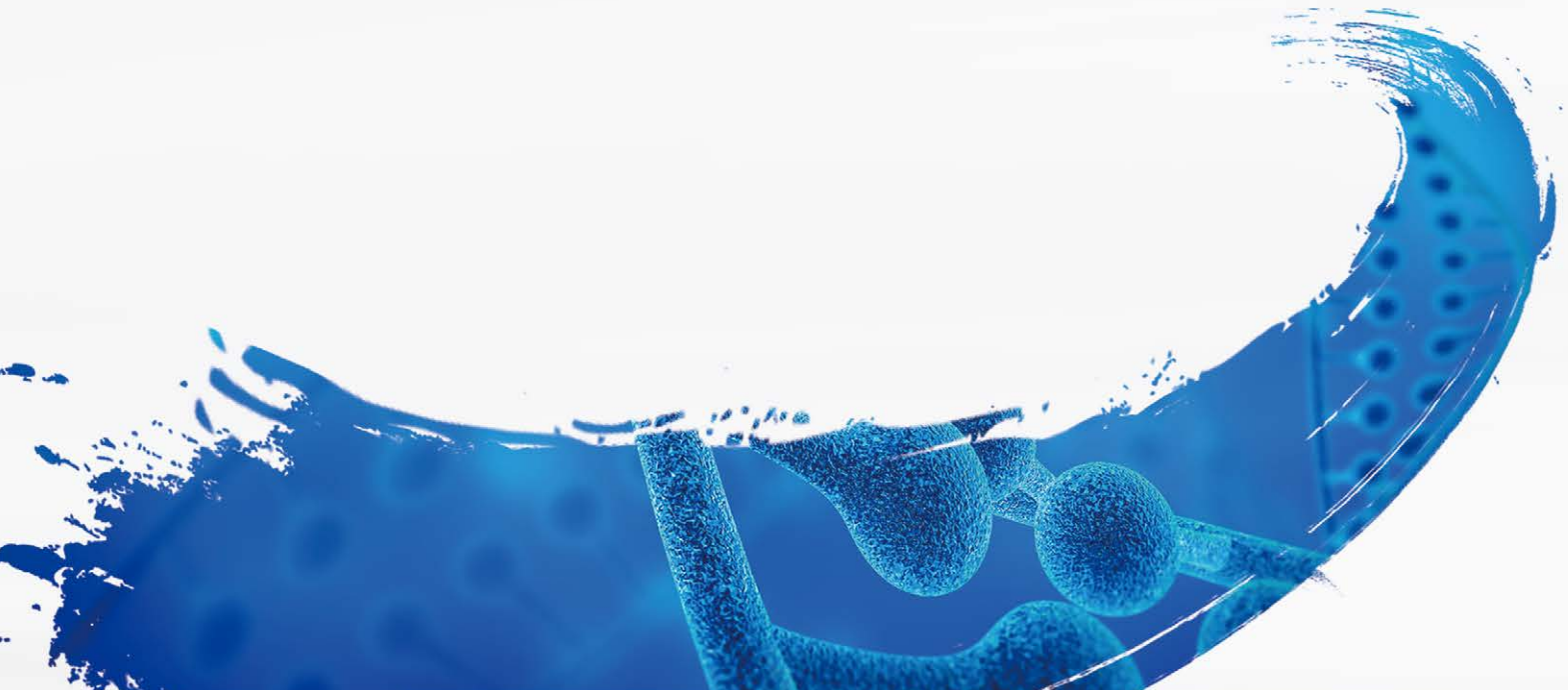
Organizational Structure of PhIRDA



- Drug R&D Specialty Committee
- Clinical Trial Research Specialty Committee
- Medicinal Policy Specialty Committee
- Pharmaceutical Innovation Investment Specialty Committee
- Innovation R&D Services Specialty Committee
- Clinical Research on Cardiovascular Drugs Specialty Committee
- International Regulatory Science Specialty Committee
- Clinical Research on Oncology Drugs Specialty Committee
- Clinical Research on Cranial Nerve Drugs Specialty Committee
- Clinical Research on Diabetes and Metabolic Disease Drugs Specialty Committee
- Digital Medicine and Innovative Therapy Specialty Committee
- Innovative Medical Devices Specialty Committee
- Cell and Gene Therapy Specialty Committee

协会领导

Leadership of PhIRDA



历任会长
Former Chairman of PhIRDA

桑国卫 Sang Guowei	中国药促会会长（2009-2012）、中国药促会荣誉会长、十一届全国人大常委会副委员长、中国工程院院士 Chairman of PhIRDA (2009-2012), Honorary Chairman of PhIRDA , Vice Chairman of the Standing Committee of Eleventh National People’s Congress, Academician of Chinese Academy of Engineering
陈启宇 Chen Qiyu	2012-2013年度会长、复星国际执行董事兼联席首席执行官 Annual Chairman 2012-2013, Executive Director & Co-CEO of Fosun International
闫希军 Yan Xijun	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 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 Sun Piaoyang	2014-2015年度会长、江苏恒瑞医药股份有限公司董事长 Annual Chairman 2014-2015, Chairman of the Board, Jiangsu Hengrui Pharmaceuticals Co., Ltd.
蒋华良 Jiang Hualiang	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 Annual Chairman 2015-2016, Academician of Chinese Academy of Sciences, Researcher, Shanghai Institute of Materia Medica, Chinese Academy of Sciences
丁列明 Ding Lieming	2016-2017年度会长、贝达药业股份有限公司董事长兼CEO Annual Chairman 2016-2017, Chairman of the Board & CEO, Betta Pharmaceutical Co., Ltd.
蒋建东 Jiang Jiandong	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 Annual Chairman 2017-2018, Academician of Chinese Academy of Engineering, Director, Institute of Pharmaceutical Science, Chinese Academy of Medical Sciences
刘殿波 Liu Dianbo	2018-2019年度会长、绿叶生命科学集团董事局主席 Annual Chairman 2018-2019, Chairman of the Board, Luye Life Sciences Group
宋瑞霖 Song Ruilin	2019-2020年度会长、中国医药创新促进会资深会长、首席专家 Annual Chairman 2019-2020, Eminent President & Chief Expert of China Pharmaceutical Innovation and Research Development Association
任晋生 Ren Jinsheng	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 Annual Chairman 2020-2021, Chairman and Chief Executive Officer, Simcere Pharmaceutical Group Limited
李 燕 Li Yan	2021-2022年度会长、齐鲁制药集团有限公司总裁 Annual Chairman 2021-2022, President, Qilu Pharmaceutical Group Co., Ltd.
李 佳 Li Jia	2022-2023年度会长、中国科学院上海药物研究所所长 Annual Chairman 2022-2023, Director, Shanghai Institute of Materia Medica, Chinese Academy of Sciences

资深会长
Eminent President

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

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

宋瑞霖
2019-2020年度会长
中国医药创新促进会首席专家

Song Ruilin
Annual Chairman 2019-2020
Chief Expert of China Pharmaceutical Innovation and Research Development Association

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

Chen Qiyu
Annual Chairman 2012-2013
Executive Director & Co-CEO, Fosun International

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.

柯尊洪
第十一届理事会副会长
成都康弘药业集团股份有限公司董事长

Ke Zunhong
Vice President of the 11th Board of Directors
Chairman of the Board, Chengdu Kanghong Pharmaceutical Group Co., Ltd.

吴晓滨
第十一届理事会副会长
百济神州全球总裁兼首席运营官

Wu Xiaobin
Vice President of the 11th Board of Directors
President and Chief Operating Officer, BeOne Medicines

现任负责人
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

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.

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, Simcere Pharmaceutical Group Limited

李 燕 副会长
齐鲁制药集团有限公司总裁

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

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

杨秋华　副会长
上海医药党委书记、董事长

Yang Qiuhua, Vice President
Secretary of the Party Committee & Chairman of the Board, SPH

吴以芳　副会长
上海复星医药（集团）股份有限公司非执行董事

Wu Yifang, Vice President
Non-executive Director of Shanghai Fosun Pharmaceutical (Group) Co., Ltd.

戴洪斌　副会长
江苏恒瑞医药股份有限公司副董事长

Dai Hongbin, Vice President
Vice Chairman, Jiangsu Hengrui Pharmaceuticals Co., Ltd.

冯　岚　副会长（驻会）
中国医药创新促进会

Feng Lan, Vice President (Resident)
China Pharmaceutical Innovation and Research Development Association

祁　彦　副会长
百济神州高级副总裁

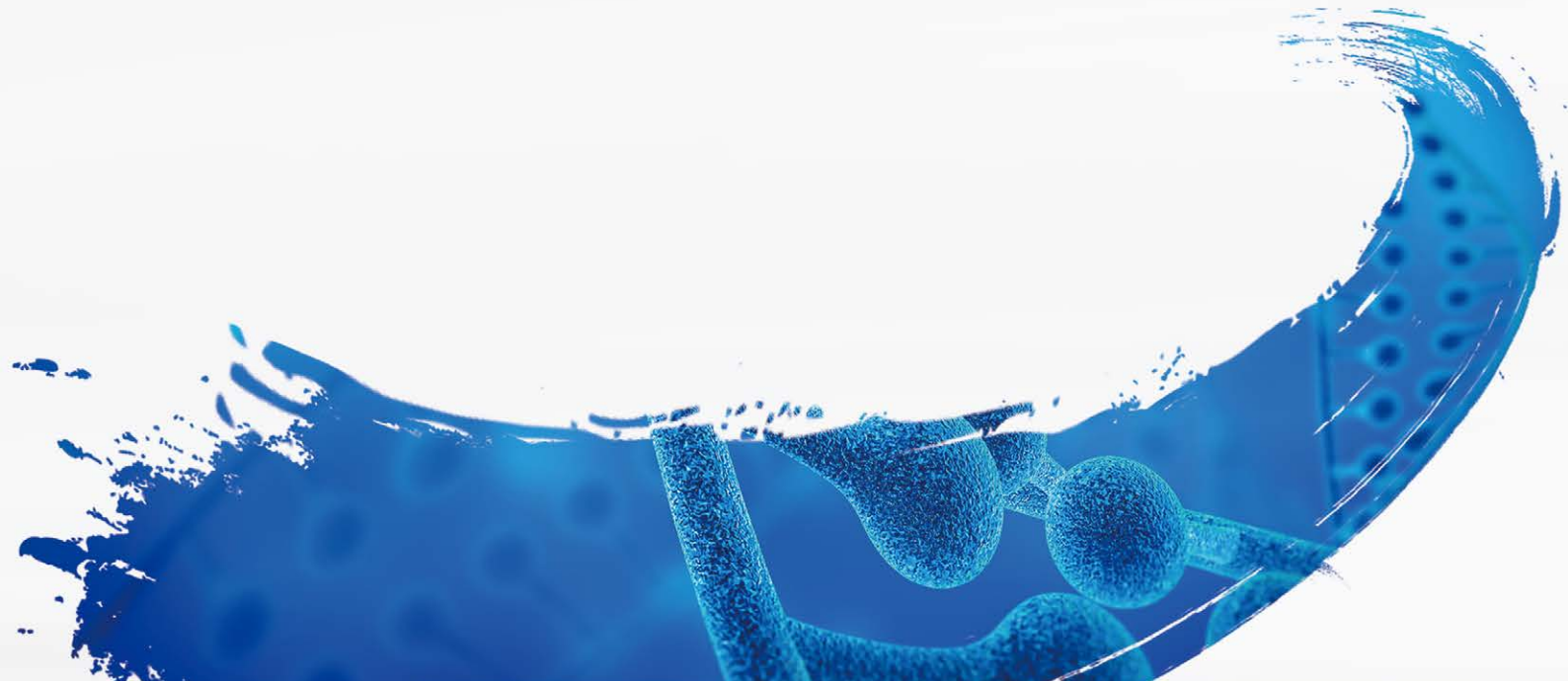
Qi Yan, Vice President
Senior Vice President, BeOne Medicines

李　捷　秘书长
中国医药创新促进会

Li Jie, Secretary-General
China Pharmaceutical Innovation and Research Development Association

专业委员会

Specialty Committees



专业委员会简介

中国药促会目前已成立12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。

在药品监管、临床研究和投融资等特殊领域，允许吸纳相关专家以个人身份加入专业委员会，围绕政策研究、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。

Introduction to Specialty Committe

At present, PhIRDA has established 12 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 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.

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.

In specialized fields including drug regulation, clinical research, and investment and financing, relevant experts could be invited to join specialty committees in their individual capacity to provide guidance and consultation on policy research, technological innovation, clinical research, investment and financing, and R&D services.

第五届药物研发专业委员会

The 5th Drug R&D Specialty Committee

张　丹　资深主任委员
昆翎医药联合创始人兼首席战略官，谱新生物联合创始人&联席董事长

Zhang Dan, Eminent Chairman
Co-founder and Chief Strategic Officer of ClinChoice Inc.
Co-founder and Co-Chairman of Jiangsu Hillgene Biopharma Co., Ltd.

王印祥　资深主任委员
北京加科思新药研发有限公司董事长兼首席执行官

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

杨大俊　资深主任委员
亚盛医药董事长兼首席执行官

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

鲁先平　资深主任委员
深圳微芯生物科技股份有限公司董事长兼总经理

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

陈　力　主任委员
华领医药技术（上海）有限公司首席执行官

Chen Li, Chairman
CEO of Hua Medicine (Shanghai) Ltd.

任　进　副主任委员
中国科学院上海药物研究所研究员

Ren Jin, Vice-Chairman
Professor, Shanghai Institute of Materia Medica, Chinese Academy of Sciences

张　翱　副主任委员
上海交通大学药学院院长

Zhang Ao, Vice-Chairman
Dean, College of Pharmaceutical Sciences, Shanghai Jiao Tong University

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中国科学院上海药物研究所副所长

Zhou Bing, Vice-Chairman
Deputy Director of Shanghai Institute of Materia Medica. Chinese Academy of Sciences

许 田 副主任委员
西湖大学遗传学讲席教授

Xu Tian, Vice-Chairman
Chair Professor of Genetics, Westlake University

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北京协和医院药物研发与评价平台主任

Luan Xiaodong, Vice-Chairman
Director of the Drug R&D and Evaluation Platform, Peking Union Medical College Hospital

苏慰国 副主任委员
和黄医药首席执行官
兼首席科学官

Su Weiguo, Vice-Chairman
CEO & CSO, HUTCHMED

房健民 副主任委员
荣昌生物联合创始人
首席执行官兼首席科学官

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

薛 群 副主任委员
北海康成制药有限公司创始人
董事长兼首席执行官

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

阎水忠 副主任委员
再鼎医药全球研发首席运营官

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

王庆华 副主任委员
上海银诺医药技术有限公司
董事长兼总经理

Wang Qinghua, Vice-Chairman
Chairman and CEO of Shanghai Innogen Pharmaceutical Technology Co., Ltd.

曹蓓莉 秘书长
华领医药技术（上海）有限公司
副总裁

Cao Beili, Secretary-General
Vice President of Hua Medicine (Shanghai) Ltd.

第四届药物临床试验专业委员会

The 4th Clinical Trial Research Specialty Committee

崔一民　主任委员
北京大学临床药理研究所所长

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

王兴河　副主任委员
首都医科大学附属北京世纪坛医院临床研究质量促进中心主任，医院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

Wang Xinghe, Vice-Chairman
Director of the Clinical Research Quality Promotion Center, Vice-Chairman of the Hospital Medical Ethics Committee, Honorary Director of the Phase I Clinical Trial Center of Beijing Shijitan Hospital, Capital Medical University

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北京大学第三医院药物临床试验机构主任

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

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

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

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首都医科大学附属北京安贞医院药事部主任、研究型病房主任、药物临床试验机构办公室主任、I期临床研究室负责人

Lin Yang, Vice-Chairman
Director of Pharmacy Department, Director of Research Ward, Director of Office of Drug Clinical Trial Institutions, and Head of Phase I Clinical Research Department, Beijing Anzhen Hospital, Capital Medical University

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清华大学医学院临床试验中心执行主任、北京清华长庚医院临床试验机构办公室主任

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

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第五届医药政策专业委员会

The 5th Medicinal Policy Specialty Committee

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卫生经济学教授

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首席专家

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研究院执行院长

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清华大学公共管理学院民生
与健康政策研究中心首席专家

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Chief Expert, Center for People's Livelihoods and Health Policy Research, School of Public and Management, Tsinghua University

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与保障专家委员会委员

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主任药师

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Director, Department of Pharmacy, Peking University First Hospital

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党委书记

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Research Investigator, School of Pharmacy, Tsinghua University

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Senior Partner, Zhong Lun Law Firm

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Senior Vice President & Chief Operating Officer, Betta Pharmaceuticals

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Executive Vice President, Hutchison MediPharma

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先声药业集团高级副总裁

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Senior Vice President, Simcere Pharmaceutical Group

第五届医药创新投资专业委员会

The 5th Pharmaceutical Innovation Investment Specialty Committee

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再鼎医药创始人、董事长
兼首席执行官

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元明资本创始合伙人

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Founding Partner of Yuanming Capital

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远创资本创始合伙人

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Founding Partner of YuanChuang Capital

梁颍宇 资深主任委员
启明创投原主管合伙人

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Former Managing Partner of Qiming Venture Partners

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华平投资董事总经理
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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博远资本创始合伙人

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Founding Partner of Biotrack Capital

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海捷投资控股集团首席合伙人

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Chief Partner of Hiyield Capital Holding Group

李凯军 副主任委员
醴泽资本管理合伙人

Kevin Li, Vice-Chairman
Managing Partner of LYZZ Capital

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复星全球合伙人
复健资本首席执行官

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Global Partners of Fosun International, Chief Executive Officer of Fosun Health Capital

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北京泰康投资管理有限公司CEO

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Chief Executive Officer of Taikang Asset Management Co., Ltd

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红杉中国合伙人

Lynn Yang, Vice-Chairman
Partner of HSG

黄晓华　副主任委员
招商局健康产业控股有限公司
总经理

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

张　莉　副主任委员
齐济投资创始管理合伙人

Lily Zhang, Vice-Chairman
Founding and Managing Partner of TTM Capital

孙佳林　副主任委员
高特佳投资集团总经理

Sun Jialin, Vice-Chairman
General Manager of GTJA Investment Group

王　珣　副主任委员
华盖医疗投资首席投资官

Cynix Wang, Vice-Chairman
CIO, Huagai Healthcare Fund

施　珑　秘书长
华平投资董事总经理

Leo Shi, Secretary-General
Managing Director, Warburg Pincus

第三届创新研发服务专业委员会

The 3rd Innovation R&D Services Specialty Committee

闻丹忆 主任委员
上海立迪生物技术股份有限公司
董事长兼执行总裁

Wen Danyi, Chairman
President & CEO of Shanghai LIDE Co., Ltd.

甄 岭 副主任委员
ClinChoice昆翎全球董事长
兼首席执行官

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

梅义将 副主任委员
浙江九洲药业股份有限公司总裁

Mei Yijiang, Vice-Chairman
President of Zhejiang Jiuzhou Pharmaceutical Co., Ltd.

李 明 副主任委员
滬港中科国际生物科技有限公司
首席执行官

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

马 健 副主任委员
深圳晶泰科技有限公司
联合创始人、首席执行官

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

刘 杨 秘书长
赛赋医药董事长

Liu Yang, Secretary-General
President of SAIFU Laboratories 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

葛均波　名誉主任委员
中国科学院院士
上海复旦大学附属中山医院
心内科主任

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

霍　勇　主任委员
北京大学第一医院
心内科首席专家

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

袁祖贻　副主任委员
西安交通大学第一附属医院
心血管病医院院长

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

陈纪言　副主任委员
广东省人民医院首席专家

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

周玉杰　副主任委员
首都医科大学附属北京安贞医院
常务副院长

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

荆志成　副主任委员
中国医学科学院北京协和医院
心内科主任

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

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华中科技大学同济医学院附属协和医院副院长

Huang Kai, Vice-Chairman
Vice President of Union Hospital, Tongji Medical College, Huazhong University of Science and Technology

耿美玉 副主任委员
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

孔祥清 副主任委员
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

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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

张 岩 副主任委员兼秘书长
北京大学第一医院心血管内科主任

Zhang Yan, Vice-Chairman & Secretary-General
Director of Cardiology Department, Peking University First Hospital

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
荣昌生物首席战略官、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
CSO of RemeGen, CMO of SDIC, Former Chief Scientist of Center for Drug Evaluation, CFDA

杜　涛　候任主任委员
深圳埃格林医药有限公司董事长

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

陈少羽　副主任委员
美国安诺波特律师事务所驻上海代表处管理合伙人

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

杜　新　副主任委员
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.

李　宁　副主任委员
上海君实生物副董事长

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

赵孝斌　副主任委员兼秘书长
海昶生物总裁、创始人

Zhao Xiaobin, Vice-Chairman & Secretary-General
President & Founder of 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
中国药科大学附属南京天印山医院科学顾问

Qin Shukui, Counselor
Scientific Consultant of Nanjing Tianyinshan Hospital Affiliated to China Pharmaceutical University

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.

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中国工程院院士

Sun Yan, Counselor
Academician of 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 Guangdong General Hospital

于金明 顾问
中国工程院院士

Yu Jinming, Counselor
Academician of Chinese Academy of Engineering

李 进 主任委员
中国药科大学附属上海高博肿瘤医院院长

Li Jin, Chairman
Director of Shanghai GoBroad Cancer Hospital Affiliated to China Pharmaceutical University

徐兵河 副主任委员
中国工程院院士

Xu Binghe, Vice-Chairman
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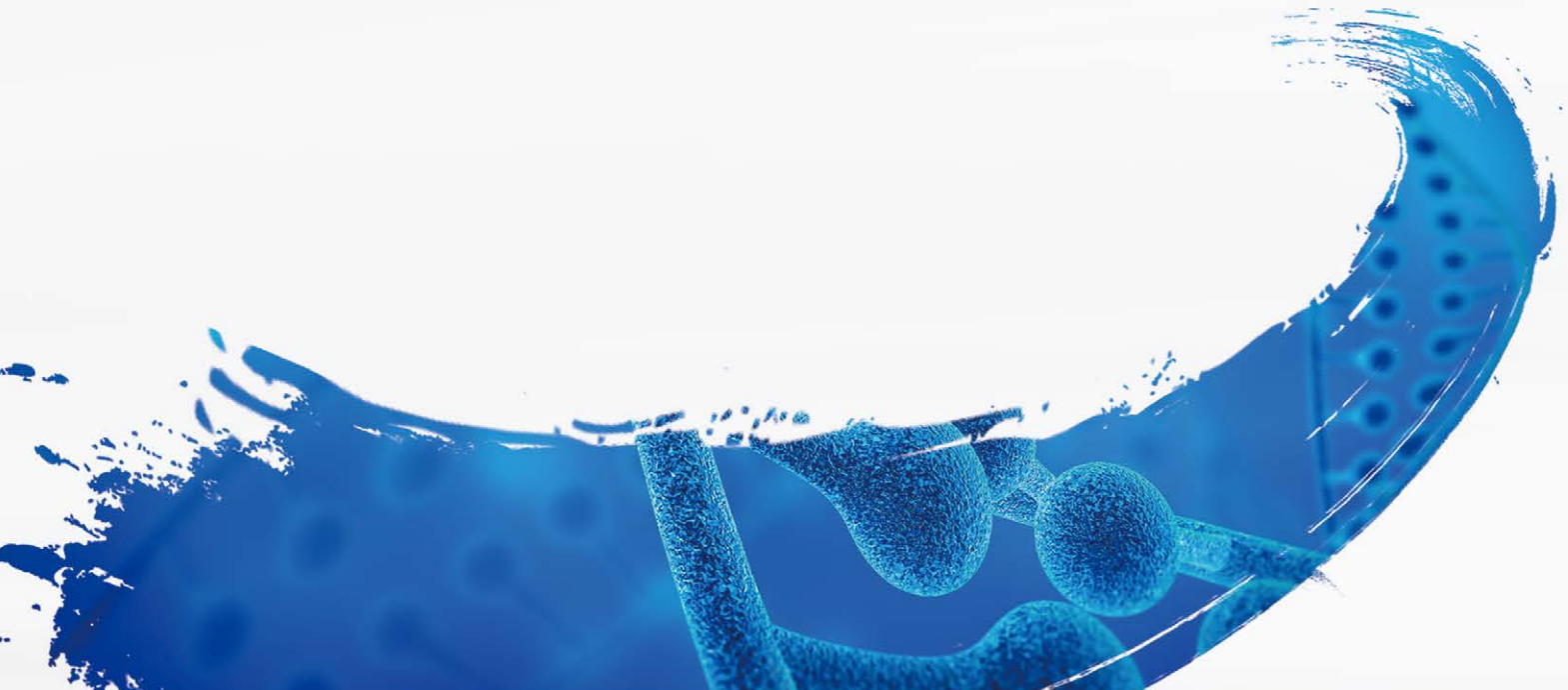

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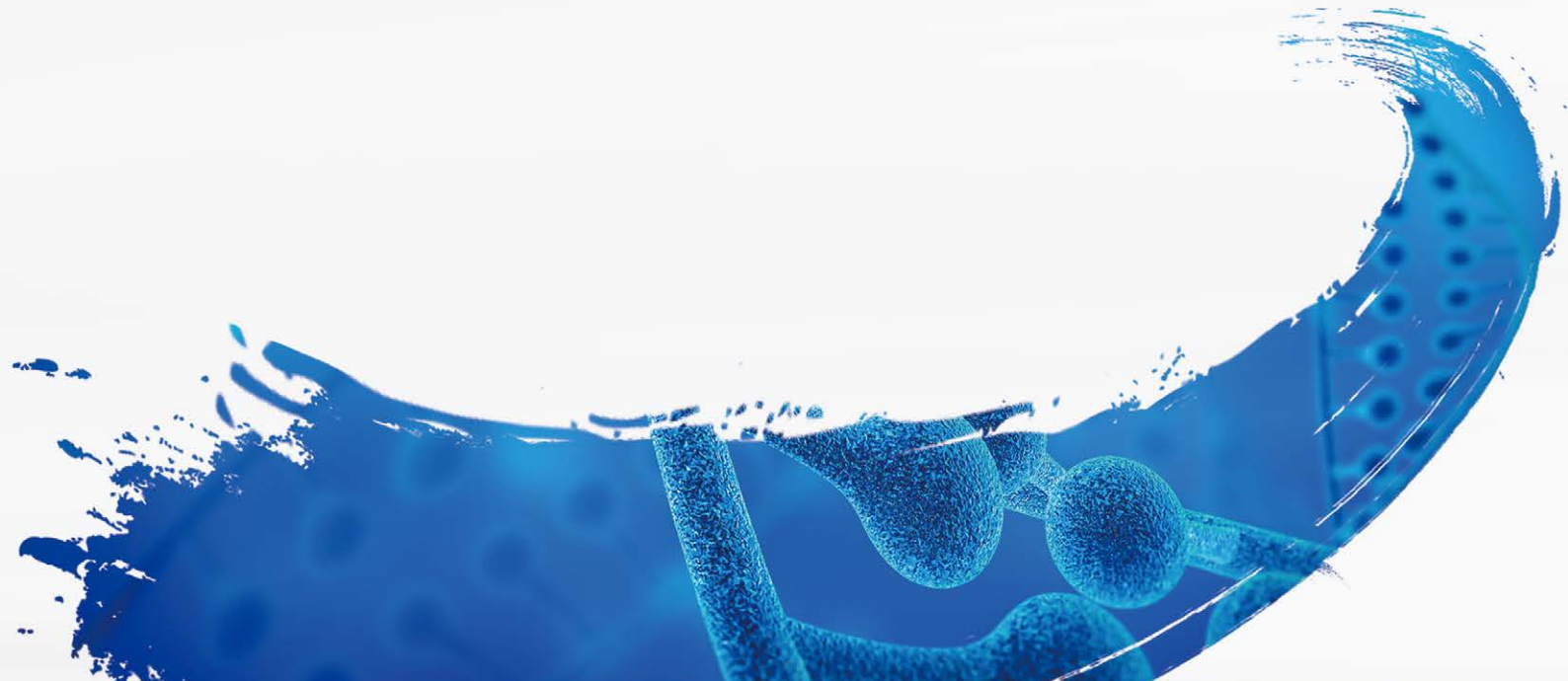

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肖瑞平 Xiao Ruiping	和其瑞医药（南京）有限公司创始人、董事长 Founder & Chairman of the Board, Hope Medicine (Nanjing) Co., Ltd.

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
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 Huang Yuesheng	北京五和博澳药业股份有限公司董事长 Chairman of the Board, Beijing Wehand-Bio Pharmaceutical Co., Ltd.
史晓峰 Shi Xiaofeng	远大医药（中国）有限公司董事长 Chairman of the Board, Grand Pharma (China) Co., Ltd.
吕向阳 Lyu Xiangyang	来凯医药科技（上海）有限公司创始人、董事长兼CEO Founder, Chairman of the Board & CEO, Laekna Therapeutics Shanghai Co., Ltd.
向宇 Xiang Yu	上海琅钰健康科技（集团）有限公司首席执行官 CEO, RareStone Group Co., Ltd.
赵大尧 Zhao Dayao	上海蔼睦医疗科技有限公司首席执行官 CEO, Shanghai AffaMed Therapeutics Co., Ltd.
张晓雷 Zhang Xiaolei	瓴路药业（上海）有限责任公司联合创始人兼首席执行官 Co-Founder & CEO, Overland Pharmaceutical (Shanghai) Co., Ltd.
董瑞平 Dong Ruiping	上海海和药物研究开发股份有限公司首席执行官 CEO, Haihe Biopharma Co., Ltd.
梁果 Liang Guo	四川三叶草生物首席执行官兼执行董事 Chief Executive Officer and Executive Director of Clover

刘利平 Liu Liping	深圳君圣泰生物技术有限公司创始人、首席执行官 Founder & CEO, HighTide Therapuetics, Inc.
龚兆龙 Gong Zhaolong	思路迪(北京)医药科技有限公司董事长兼首席执行官 Chairman of the Board & CEO, 3D Medicines Inc.
刘滨磊 Liu Binlei	武汉滨会生物科技股份有限公司创始人、董事长兼总经理 Founder, Chairman of the Board & General Manager, Binhui Biopharmaceutical Co., Ltd.
贾祥波 Jia Xiangbo	无锡智康弘义生物科技有限公司创始人、董事长 Founder & Chairman of the Board, Biocity Biopharmaceutics Co., Ltd.
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.
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
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.
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	苏州亦诺微医药科技有限公司董事长、首席执行官 Chairman & CEO, ImmVira

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
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.
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.
严庞科 Yan Pangke	海思科医药集团股份有限公司总经理 General Manager, Haisco Pharmaceutical Group Co., Ltd.
惠欣 Hui Xin	上海璎黎药业有限公司董事长 Chairman, Shanghai Yingli Pharmaceutical Co., Ltd.
邹晓明 Zou Xiaoming	维亚臻生物技术(苏州)有限公司首席执行官 Chief Executive Officer, Visirna Therapeutics (Suzhou) Co., Ltd.
范迅 Fan Xun	上海济煜医药科技有限公司副总经理 Vice President, Shanghai Jemincare Pharmaceutical Co., Ltd.
武术 Wu Shu	南京传奇生物科技有限公司高级副总裁、大中华区总经理 Senior Vice President, General Manager, Greater China, Nanjing Legend Biotech Co., Ltd.
王朝东 Wang Chaodong	武汉朗来科技发展有限公司创始人、董事长 Chairman, Wuhan Createrna Science and Technology Co., Ltd.
朱义 Zhu Yi	四川百利天恒药业股份有限公司董事长、总经理兼任首席科学官 Chairman, CEO & CSO, Sichuan Biokin Pharmaceutical Co., Ltd.
安猛 An Meng	广州康臣药业有限公司董事局主席 Chairman, Guangzhou Kangchen Pharmaceutical Co., Ltd.
张登科 Zhang Dengke	西安新通药物研究股份有限公司董事长 Chairman, Xi'an Xintong Pharmaceutical Research 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.
楼胜琼 Lou Shengqiong	杭州星源未来科技有限公司总经理 General Manager, Hangzhou Astrocyte Technology 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.
张戬 Zhang Jian	兰胜供应链管理 (上海) 有限公司董事长兼CEO Chairman & CEO, Lansheng Supply Chain Management (Shanghai) Co., Ltd.
张天泽 Zhang Tianze	零氪科技 (北京) 有限公司首席执行官 CEO, LinkDoc Technology Co., Ltd.
温书豪 Wen Shuhao	晶泰科技联合创始人、董事长 Co-Founder and Chairman, XtalPi
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.

方攀峰 Fang Panfeng	苏州镁伽科技有限公司研发副总裁 R&D VP, 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.
吕东 Lyu Dong	高瓴资本董事总经理 Co-CIO and Partner, Hillhouse Capital
田源 Tian Yuan	元明资本创始合伙人 Founding Partner, YuanMing Capital
朱晋桥 Zhu Jinqiao	倚锋资本董事长 Chairman of the Board, Efung Capital
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 President, Ping An Bank
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.
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.
张莉 Zhang Li	齐济(苏州)创业投资有限公司创始管理合伙人 Founding and Managing Partner, TTM(Suzhou) Venture Capital Co., Ltd.
甄岭 Zhen Ling	ClinChoice昆翎全球董事长兼首席执行官 Global Chairman & CEO, ClinChoice
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.
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.
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
宓子厚 Mi Zihou	艾昆纬亚太区总裁 President, Asia Pacific, IQVIA
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.
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
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.

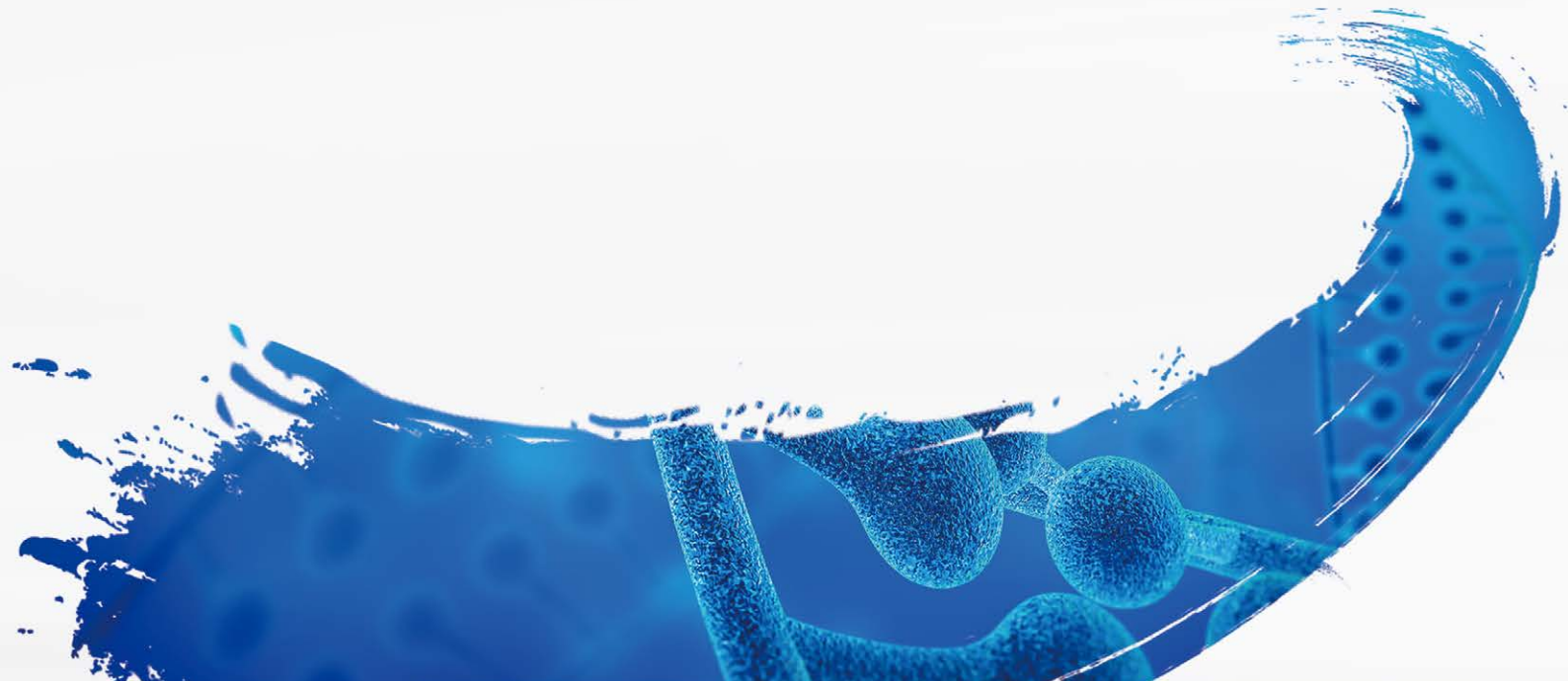
高楠 Gao Nan	北京高博医疗科技集团有限公司副总裁 Vice President, GoBroad Healthcare Group
叶敏 Ye Min	北京大学药学院院长 Dean, Peking University School of Pharmaceutical Sciences
王建新 Wang Jianxin	复旦大学药学院党委书记 Secretary of the Party Committee, School of Pharmacy, Fudan University
李卓荣 Li Zhuorong	中国医学科学院北京协和医学院医药生物技术研究所原副所长 Former deputy Director, Institute of Medicinal Biotechnology, Chinese Academy of Medical Sciences & Peking Union Medical College
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
张翱 Zhang Ao	上海交通大学药学院院长 Dean, School of Pharmaceutical Sciences, Shanghai Jiao Tong University
李子孝 Li Zixiao	首都医科大学附属北京天坛医院院长助理，神经病学中心副主任 Assistant to the Dean, Deputy Director of the Neurology Center

重要活动

（2024 年 1 月 -2024 年 12 月）

Important Events

(January,2024-December,2024)



PART-1

加强党建引领，筑牢思想与行动根基

Strengthen Party Building Guidance,
Consolidate the Foundation of Thought and Action

中国药促会党支部始终坚持以习近平新时代中国特色社会主义思想为指导，深入贯彻党的二十大和二十届历次全会精神，扎实推进党支部标准化、规范化建设，不断提高党建工作质量，以党建引领协会高质量发展。聚焦政治建设，坚持“第一议题”制度，及时跟进学习贯彻习近平总书记重要讲话和重要指示批示精神；根据全国性行业协会商会党委和中国工业经济联合会党委统一部署要求，扎实开展党纪学习教育，进一步增强支部党员的纪律意识，教育引导党员干部学纪、知纪、明纪、守纪；按照发展党员工作的有关规定，我会党支部 2 名预备党员期满转正，并确定 2 名积极分子。

The Party branch of PhIRDA has consistently adhered to the Xi Jinping Thought on Socialism with Chinese Characteristics for a New Era as its guide, thoroughly implementing the guiding principles of the 20th CPC National Congress and subsequent plenary sessions. The Party branch of PhIRDA has steadily advanced the standardization and regularization of Party branch construction, to continuously enhance Party building work for the guidance of the high-quality development of PhIRDA. Focusing on political advancement, the branch upholds the “First Topic” system, promptly following up on and implementing the important speeches and instructions of General Secretary Xi Jinping. In accordance with the unified deployment requirements of the CPC Committee of National Industry Associations and Chambers of Commerce and the CPC Committee of China Federation of Industrial Economics, the branch has conducted solid disciplinary education, further enhancing Party members’ awareness of discipline, and guiding Party members and cadres to learn, know, understand, and observe Party discipline. Following the relevant regulations on Party member development, two probationary members of our Party branch have been granted full membership, and two active candidates have been identified.

集体学习二十届三中全会精神
Studying the Spirit of the Third Plenary Session of the 20th CPC Central Committee

党支部书记冯岚同志讲党课
Party Branch Secretary Feng Lan Delivers a Party Lecture

参观中国共产党历史展览馆
Visit Museum of the Communist Party of China

中国药促会党支部与华润双鹤党委开展联合主题党日活动·西柏坡
PhIRDA’s Party Branch and the Party Committee of China Resources Double-Crane Pharmaceutical held a Joint Themed Party Day Event · Xibaipo

PART-2

立足重点工作会议，明方向绘蓝图谱新篇

From Core Meetings to New Frontiers: Indicate Direction and Draw a New Chapter

第十一届理事会第五次会议（2024 年 2 月 22 日・北京）

The Fifth Meeting of the 11th Board of Directors (February 22, 2024・Beijing)

我会会领导张抒扬、宋瑞霖、李佳、陈启宇、丁列明、刘殿波、冯岚，监事舒畅，中国药科大学教授吴晓明等第十一届理事（代表）及会员代表共 80 余人参加会议；我会专委会主任委员胡欣、崔一民、何如意、王广志等专家受邀出席会议。

会议投票选举北京协和医院院长张抒扬担任我会 2024 年度会长，审议通过《关于成立换届工作领导小组的议案》。我会秘书长冯岚向理事会做工作报告，并提出 2024 年度重点工作建议。与会代表围绕我会 2022-2023 年度重点工作及未来工作建议展开讨论并达成共识。

PhIRDA leadership Zhang Shuyang, Song Ruilin, Li Jia, Chen Qiyu, Ding Lieming, Liu Dianbo, Feng Lan, and Supervisor Shu Chang and and Professor Wu Xiaoming from China Pharmaceutical University, as well as over 80 representatives of the 11th Board of Directors (representatives) and representatives of members attended the meeting. The Chairmen of the PhIRDA Speciality Committees including Hu Xin, Cui Yimin, He Ruyi, and Wang Guangzhi were also invited to attend.

The meeting held a vote，and elected Zhang Shuyang, President of Peking Union Medical College Hospital, as the PhIRDA Chairman for 2024 and reviewed and approved the *Proposal on the Establishment of the Leading Group for the Election of the 12th Board of Directors.* Secretary-General Feng Lan delivered a work report to the Board and proposed key work priorities for 2024. The participants discussed and reached a consensus on PhIRDA’s key activities in 2022-2023 and suggestions for future work.

2022-2023 年年度会长李佳为新当选会长张抒扬颁发证书

Chairman Li Jia (2022-2023) presented a certificate to newly elected Chairman Zhang Shuyang

会议就新药研发趋势、临床赋能、化药首发价格机制等业内关注的热点话题进行了交流和讨论。与会领导、专家和参会代表结合实际案例积极发言，并形成多项共识，为未来行业发展打下坚实基础。

The meeting featured exchanges and discussions on hot topics of industry concerns, including new drug development trends, clinical empowerment, and pricing mechanisms for original chemical drugs. The attending leaders, experts, and representatives actively shared their insights based on practical cases and reached several consensuses, laying a solid foundation for future industry development.

全体合影
Group Photo

2024 年会长会议扩大会议暨换届工作领导小组工作会议（2024 年 5 月 30 日・杭州）
2024 President Board Meeting and the Work Meeting of the Leading Group for the Election of the 12th Board of Directors (May 30, 2024・Hangzhou)

换届工作领导小组成员，我会会长张抒扬，执行会长宋瑞霖，副会长陈启宇、丁列明、蒋建东、刘殿波、李佳、赵勇、吴晓滨，秘书长冯岚，监事邵蓉、舒畅，会员代表房健民、许小林出席。此外，中国药促会国际创新药物监管专委会主委何如意、创新研发服务专委会主委闻丹忆，西湖大学副校长许田以及部分我会副会长单位和会员单位代表受邀出席。

Members of the Leading Group for the Election of the 12th Board of Directors in attendance included: Chairman Zhang Shuyang, Executive President Song Ruilin, Vice Presidents Chen Qiyu, Ding Lieming, Jiang Jiandong, Liu Dianbo, Li Jia, Zhao Yong, Wu Xiaobin, Secretary-General Feng Lan, Supervisors Shao Rong and Shu Chang, and member representatives Fang Jianmin and Xu Xiaolin. Additionally, He Ruyi, Chairman of International Regulatory Sciences Specialty Committee, Wen Danyi, Chairman of Innovation R&D Services Specialty Committee, Xu Tian, Vice President of Westlake University, along with representatives from some Vice-President organizations and members were invited to attend.

会议现场
Plenary Meeting

会议深入讨论了第十二届理事会换届选举方案，就理事会延期、章程修订和第十二届负责人和监事候选人等问题进行充分沟通，换届工作领导小组就相关调整达成一致意见。会议总结了第十一届理事会第五次会议以来的重点工作。

参会嘉宾围绕“医保支付、商业保险、数据安全”等热点问题展开探讨。结合行业发展需求提出宝贵意见建议，形成多项共识，呼吁行业之所需，为政策制定提供可靠借鉴。

The meeting thoroughly discussed the election plan for the 12th Board of Directors, with extensive communications on issues including extension of board term, amendments of the Constitution, and candidates for the 12th leadership and supervisors. The Leading Group for the Election of the 12th Board of Directors reached consensus on relevant adjustments. The meeting also summarized key work accomplishments since the Fifth Meeting of the 11th Board of Directors.

Participants engaged in discussions on hot topics including medical insurance payment, commercial insurance and data security, providing valuable suggestions based on industry development needs, reached consensuses, addressed industry requirements, and shared insights for policy-making.

全体合影
Group Photo

PART-3

汇聚多元思想，打造高水平对话平台

Bring Together Diverse Perspectives, Build a High-Level Dialogue Platform

第二届合肥生物医药创新与产业大会（2024 年 9 月 6 日 -7 日・合肥）

The Second Hefei Biopharmaceutical Innovation & Industry Conference (September 6-7, 2024・Hefei)

由我会与合肥综合性国家科学中心大健康研究院、合肥综合性国家科学中心办公室、安徽省生命健康产业推进组办公室、中国科协生命科学联合体等单位共同组织的第二届合肥生物医药创新与产业大会在合肥隆重举行。

多位两院院士、安徽省政府部门领导、专家学者出席大会，共同探讨技术生态，展望行业和产业的未来。大会共组织十余场论坛、路演，邀请百余位生物医药创新产业专家，聚焦生物医药前沿，围绕抗体药物、细胞治疗药物、基因治疗药物等创新药物研究、开发、产业化与监管的热点和难点问题，开展学术交流和产业合作。

The Second Hefei Biopharmaceutical Innovation & Industry Conference, co-hosted by PhIRDA, the Institute of Health and Medicine, Hefei Comprehensive National Science Center, the Office of Hefei Comprehensive National Science Center, Office of the Anhui Provincial Life and Health Industry Promotion Group, and China Union of Life Sciences Societies was held in Hefei.

Academicians from the Chinese Academy of Sciences and the Chinese Academy of Engineering, along with senior officials from the People’s Government of Anhui Province and industry experts, attended the conference to explore the technological ecosystem and envision the future of the industry. The conference set up over ten forums and roadshows, bringing together more than 100 experts from the biopharmaceutical innovation sectors, focusing on cutting-edge developments in biopharmaceuticals, conducting cooperation and exchanges on drug R&D, industrialization and regulatory challenges and opportunities of innovative therapies including antibody drugs, cell therapies, and gene therapies.

田志刚 中国工程院院士

Tian Zhigang, Academician of the Chinese Academy of Engineering

宋瑞霖 中国药促会执行会长

Song Ruilin, Executive President of PhIRDA

丁健 中国工程院院士

Ding Jian, Academician of the Chinese Academy of Engineering

王广基 中国工程院院士

Wang Guangji, Academician of the Chinese Academy of Engineering

王军志 中国工程院院士

Wang Junzhi, Academician of the Chinese Academy of Engineering

常俊标 中国科学院院士

Chang Junbiao, Academician of the Chinese Academy of Sciences

会议现场
Plenary Meeting

第二届溶瘤病毒创新与合作大会（2024 年 10 月 26 日 -27 日・武汉）
The Second Interdisciplinary Oncolytic Virotherapy Innovation Convention (October 26-27, 2024・ Wuhan)

在我会和武汉东湖新技术开发区管理委员会指导下，由艾美达医药咨询主办，武汉国家生物产业基地建设服务中心、武汉滨会生物科技股份有限公司协办的第二届溶瘤病毒创新与合作大会在武汉召开。

The Second Interdisciplinary Oncolytic Virotherapy Innovation Convention (IOVIC), jointly guided by PhIRDA and Administrative Committee of Wuhan East Lake High-tech Development Zone, was held in Wuhan. The second IOVIC was hosted by the iMeta Health Information Consulting Co., Ltd. and co-organized by the Wuhan National Bio-industry Base and Binhui Biopharmaceutical.

本次大会汇集溶瘤病毒领域权威专家学者，围绕溶瘤病毒行业药物基础研究及临床转化、临床及药物开发策略、商业及出海以及 FDA 审评等行业重点环节展开交流和讨论。

发布仪式嘉宾合照
Group Photo of Launching Ceremony

会议现场
Plenary Meeting

The second IOVIC brought together leading experts and scholars in the field of oncolytic virotherapy to exchange ideas and discuss key industry topics, including basic research and clinical translation of oncolytic virus therapies, clinical and drug development strategies, commercialization and international expansion, as well as review and approval policies of FDA.

第九届医药创新与投资大会（2024 年 11 月 30 日 -12 月 1 日・广州）
2024 China BioMed Innovation and Investment Conference (November 30-Decemebr 1, 2024・Guangzhou)

搭建多维连接桥梁，构筑政产学研用资多元对话平台。我会联合香港交易所、艾美达咨询共同主办的第九届医药创新与投资大会在广州盛大召开。

本届大会特设 9 个主题路演专场、9 场精彩的专题论坛 , 近 100 个路演项目、50 多个精彩报告。聚焦创新医药行业热点痛点，利用大湾区区域地理优势搭建沟通桥梁，促进全球生物医药行业的企业家、科学家和投资者之间的合作与投资，共同推动我国生物医药产业制度创新、技术创新与产业升级。

Building multidimensional bridges to foster a platform for dialogue among government, industry, academia, research, application, and capital, the 2024 China BioMed Innovation and Investment Conference (CBIIC), co-hosted by PhIRDA, Hong Kong Exchanges and Clearing Limited (HKEX), and iMeta Health Information Consulting, was held in Guangzhou.

2024 CBIIC featured 9 roadshows sessions, including nearly 100 roadshow projects, and 9 panel forums, involving over 50 insightful keynote speeches. Centered on addressing key challenges and trends in the innovative pharmaceutical industry, 2024 CBIIC leveraged the geographical advantages of the Greater Bay Area to facilitate communication and collaboration among global biopharmaceutical entrepreneurs, scientists, and investors, aiming to drive institutional and technological innovation and advance industrial upgrade in China’ s biopharmaceutical industry.

开幕式嘉宾
VIP Guests of Opening Ceremony

张抒扬 中国药促会会长、北京协和医院院长
Zhang Shuyang, Chairman of PhIRDA, President of Peking Union Medical College Hospital

王胜 广东省政府党组成员、副省长
Wang Sheng, Member of Leading Party Members’ Group and Vice Governor of the People’ s Government of Guangdong Province

赖志鸿 广州市副市长
Lai Zhihong,
Vice Mayor of Guangzhou Municipal People’ s Government

朱民 中国国际经济交流中心资深专家委员会委员、IMF 原副总裁
Zhu Min, Member of the Senior Expert Advisory Committee of the China Center for International Economic Exchanges, Former Deputy Managing Director of the IMF

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

梁颍宇 中国药促会医药创新投资专委会主任委员、启明创投主管合伙人
Nisa Leung, Chairman of PhIRDA Pharmaceutical Innovation Investment Specialty Committee, Managing Partner of Qiming Venture Partners

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

鲁晓缇 中国药促会副秘书长
Lu Xiaoti, Deputy Secretary-General of PhIRDA

主题讨论：秉初心，破内卷，筑梦原始创新

Panel Discussion: Stay Committed, Break Involution, Cultivate Original Innovation

（从左至右：李佳、孙飘扬、刘殿波、丁列明、吴晓滨、王广志）

Li Jia, Sun Piaoyang, Liu Dianbo, Ding Lieming, Wu Xiaobin, Wang Guangzhi (From Left to Right)

主题讨论：持耐心，立信心，共创新质未来

Panel Discussion: Maintain Patient, Build Confidence, Embrace a New Quality Future

（从左至右：张莉、陈启宇、邱华伟、魏大华、张蕾娣、徐经纬、李蕾）

Lily Zhang, Chen Qiyu, Qiu Huawei, Wei Dahua, Zhang Leidi, Johnson Chui, Allen Li (From Left to Right)

开幕式现场
Opening Ceremony

分会场
Parallel Session

首届“湾区之星”生物医药源头创新大会（2024 年 12 月 3 日・深圳）
The First “Star of the Greater Bay Area” Biopharmaceutical Original Innovation Forum (December 3, 2024・Shenzhen)

由我会主办，深圳市发展和改革委员会、深圳市医药和医疗器械产业办公室指导，上海复星医药（集团）股份有限公司承办的首届“湾区之星”生物医药源头创新大会在深圳成功举办。

立足深圳、聚焦粤港澳大湾区。大会邀请到顶尖高校科研院所的院士和科学家、相关政府部门领导、临床研究专家学者、头部风险投资人等 200 余人出席会议，围绕“激活源头创新第一公里”，从科学发现、科学转化、投资孵化、企业赋能、政策指引等方面探讨源头创新的关键点和路径。

2024 the First “Star of the Greater Bay Area” Biopharmaceutical Original Innovation Forum (BOIF), hosted by PhIRDA, co-organized by the Development and Reform Commission of Shenzhen Municipality and Shenzhen Pharmaceutical and Medical Device Industry Office, was held in Shenzhen.

Based in Shenzhen and focused on the Guangdong-Hong Kong-Macao Greater Bay Area, the BOIF brought together over 200 participants, including academicians and scientists from top leading universities and research institutions, government officials, clinical research experts, prominent venture capitalists. Centered on the theme of “Energizing the First Mile of Original Innovation,” the discussions explored key points and pathways for original innovation, spanning scientific discovery, translational research, investment incubation, enterprise empowerment, and policy guidance.

郭子平 深圳市发展和改革委员会党组书记、主任

Guo Ziping, Party Secretary and Director of the Shenzhen Development and Reform Commission

饶子和 中国科学院院士、清华大学教授，全国政协原常委、南开大学原校长

Rao Zihe, Academician of the Chinese Academy of Sciences, Professor at Tsinghua University, Former Member of the Standing Committee of the CPPCC National Committee, Former President of Nankai University

高福 中国科学院院士、中国科学院微生物研究所病原微生物与免疫学重点实验室主任、国家自然科学基金委员会原副主任

Gao Fu, Academician of the Chinese Academy of Sciences, Director of the Key Laboratory of Pathogenic Microbiology & Immunology at the Institute of Microbiology, Chinese Academy of Sciences, Former Vice President of the National Natural Science Foundation of China

陈志南 中国工程院院士、
转化医学国家重大科技基础设施（西安）主任

Chen Zhinnan, Academician of the Chinese Academy of Engineering, Director of the National Facility for Translational Medicine (Xi’ an)

宋瑞霖 中国药促会执行会长

Song Ruilin, Executive President of PhIRDA

卢毓琳 香港生物医药创新协会会长

Lo Yuk Lam, Chairman of the Hong Kong Bio-Med Innotech Association

John R. Speakman 深圳理工大学药学院讲席教授、欧洲科学院院士、中国科学院外籍院士、美国科学院外籍院士

John R. Speakman, Chair Professor at the College of Pharmacy, Shenzhen Technology University, Academician of the European Academy of Sciences, Foreign Academician of the Chinese Academy of Sciences, Foreign Academician of the National Academy of Sciences (NAS) of the United States

主题讨论：创新生态—湾区生物医药产业高质量发展之路
Panel Discussion: The Path to High-Quality Development of the Biopharmaceutical Industry in GBA
（从左至右：王可心、刘殿波、叶宇翔、张蕾娣、陈有海、陈力、黎慧来）
Wang Kexin, Liu Dianbo, Ye Yuxiang, Zhang Leidi, Chen Youhai, Chen Li, Li Huilai (From Left to Right)

主题讨论：创新战略—Biotech 早期战略布局与成长之路探索
Panel Discussion: Innovation Strategy: Exploration of Strategy and Growth Path for Biotech in Early Stage
（从左至右：李凡、王国玮、田文志、邹晓明、回爱民、肖昌春、沈蓉）
Li Fan, Wang Guowei, Tian Wenzhi, Zou Xiaoming, Hui Aimin, Xiao Changchun, Shen Rong (From Left to Right)

主题讨论：创新引擎—当生物医药遇到人工智能
Panel Discussion: Innovation Engine:When Biopharmaceuticals Meet Artificial Intelligence
（从左至右：王兴利、张绪穆、陈杰、马健、乔楠、刘伟、潘颖）
Wang Xingli, Zhang Xumu, Chen Jie, Ma Jian, Qiao Nan, Liu Wei, Pan Ying (From Left to Right)

PART-4

发挥高端智库作用，聚智赋能新质生产力

Maximize Think Tank Potential,
Drive New Quality Productive Forces

积极建言献策，促进全链条支持医药创新政策

Actively Submit Advices to Governments, Facilitate Full-Chain Pharmaceutical Innovation

我会充分发挥高端智库优势，聚焦创新发展的矛盾与问题，向国家相关部委提交建议报告，推动产业高质量发展、解决行业急难愁盼。

PhIRDA fully leverages its advantages as a high-level think tank, focusing on challenges and issues in innovative development, submitting reports to relevant national ministries and commissions to promote high-quality industrial development and address urgent industry concerns.

捕捉产业动向，以课题研究助力医药创新环境建设
Capture Industry Trends, Support Pharmaceutical Innovation Environment Through Research Studies

受北京市卫生健康委委托，我会持续开展“北京市研究型病房示范单位建设动态评估”工作，客观评估各示范单位在研究型病房基本建设、临床研究和成果转化方面取得的建设成效，总结第二批研究型病房 3 年建设成效，动态整理第三批研究型病房建设的阶段性成果，形成总结评估报告及政策建议，以期推动临床实践与科研创新的紧密结合，形成创新周期的良好闭环。

Entrusted by Beijing Municipal Health Commission, PhIRDA continued to conduct the “Dynamic Assessment of Research-oriented Ward Demonstration Units in Beijing.” PhIRDA objectively evaluated the achievements of demonstration units in basic construction of research wards, clinical research, and results transformation. The assessment summarizes the three-year construction outcomes of the second batch of research wards and dynamically collected the results of the third batch of research ward construction. A comprehensive evaluation report with suggestions has been formulated, aiming to promote close integration between clinical practice and scientific innovation, thus forming a positive cycle of innovation.

“研究型病房建设评估指标体系”专家研讨会（2024 年 11 月 22 日・北京）
Expert Seminar on the Evaluation Index System for Research-Oriented Ward Construction (November 22, 2024・Beijing)

围绕行业发展的痛点堵点问题，我会积极开展课题研究，以期持续完善产业创新与国际化的发展生态。

PhIRDA conducted research on the pain points and bottlenecks in industry development, aiming to continuously improve the ecosystem for industrial innovation and internationalization.

“中国创新药出海技术路径研究”结题会
（2024 年 1 月 3 日・北京）
Project Closure Meeting of Study on the Technical Pathway for China’s Innovative Drugs Going Global (January 3, 2024・Beijing)

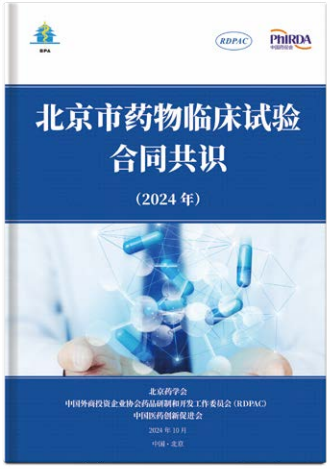
“参照药品遴选方法学共识研究”结题会
（2024 年 6 月 20 日・上海）
Project Closure Meeting of Study on the Technical Pathway for China’s Innovative Drugs Going Global (June 20, 2024・Shanghai)

“中国创新器械审评制度改革研究”结题会
（2024 年 9 月 18 日・北京）
Project Closure Meeting of Reform in China’s Review and Approval System for Innovative Medical Devices (September 18, 2024・Beijing)

“国际化背景下创新药定价机制研究”开题会
（2024 年 9 月 29 日・北京）
Kick-off Meeting for the Research on Pricing Mechanisms for Innovative Drugs in the Context of Internationalization (September 29, 2024・Beijing)

在北京市卫健委指导下，我会联合有关单位开展“临床试验效能提升研究”系列课题研究，形成并发布《北京市药物临床试验合同共识》。

Under the guidance of Beijing Municipal Health Commission, PhIRDA collaborated with relevant organizations to conduct a series of research projects on Clinical Trial Efficiency Enhancement, leading to the development and release of *The Beijing Consensus on Drug Clinical Trial Contracts.*



反映行业诉求，推动政策体系完善和行业高质量发展
Reflect Industry Demands, Promote Policy System Improvement and Advance High-Quality Development

财政部国际经济关系司莅临我会调研座谈（2024 年 6 月 28 日·北京）
Seminar with Officials from Department of International Economic Relations of the Ministry of Finance (June 28, 2024 · Beijing)

我会执行会长宋瑞霖带队拜会国家药监局医疗器械注册管理司、医疗器械技术审评中心（2024 年 8 月 6 日・北京）
Executive President Song Ruilin led a delegation to meet with relevant leaders from Department of Medical Device Registration and Center for Medical Device Evaluation of NMPA. (August 6, 2024・Beijing)

双方就“医疗器械产品风险界定、优化监管政策引领医疗器械有效创新、进一步提升审评能力与效率、建立药械创新协同机制”等话题展开交流并提出建议。

Participants engaged in discussions on topics including defining risks associated with medical device products, optimizing regulatory policies to foster effective innovation in medical devices, enhancing review capabilities and efficiency, and establishing a collaborative mechanism for drug and medical device innovation, while also offering suggestions.

国家发展改革委价格成本和认证中心莅临我会开展药品注册收费改革专题调研并召开企业座谈会调研（2024 年 9 月 11 日・北京）
Senior officials from the Center for Price Cost Investigation and Authentication, National Development and Reform Commission visited PhIRDA, conducting a corporate symposium (September 11, 2024・Beijing)

受国家药监局药审中心委托，我会组织会员企业参加“鼓励和促进罕见病药物创新研发交流会”（2024 年 12 月 20 日·北京）

Entrusted by the Center for Drug Evaluation of NMPA, PhIRDA organized members to attend the Symposium on Encouraging and Promoting Innovation and R & D of Rare Disease Drugs (December 20, 2024 · Beijing).

拓宽发声渠道，扩大行业影响力
Expand Communication Channels, Enhance Industry Influence

医药政策研究专栏

- 东盟医药市场机遇与挑战 | 创新药出海专题系列
  ASEAN Pharmaceutical Market: Opportunities and Challenges | Special Series on Innovative Drug Globalization
- 创新医疗器械改革系列丨如何从分类层面助力医疗器械审评制度改革
  Innovative Medical Device Reform Series | How to Support Medical Device Review System Reform Through Classification
- FDA 经验启示 | 改革药品注册收费制度，进一步深化审评能力建设
  FDA Experience and Revelation | Reforming Drug Registration Fee System to Further Enhance Review Capabilities
- 创新药定价难题最优解在哪里?
  What’s the Optimal Solution for Innovative Drug Pricing Challenges?
- 创新医疗器械改革系列丨持续优化分类管理 提高监管效率的思考
  Innovative Medical Device Reform Series | Continuous Optimization of Classification Management and Improving Regulatory Efficiency
- 监管国际化推动产业国际化 | 创新药出海专题报告
  International Regulatory Alignment Driving Industry Globalization | Special Report on Innovative Drug Globalization
- 创新医疗器械改革系列丨集权与分权监管模式的对比与探讨
  Innovative Medical Device Reform Series | Comparison and Analysis of Centralized versus Decentralized Regulatory Models
- 创新医疗器械改革系列丨关于完善我国医疗器械特别审评通道的思考
  Innovative Medical Device Reform Series | Thoughts on Improving China’s Special Review Pathway for Medical Devices

发表学术文章、出版研究报告，为政策制定与完善提供参考。

Publish academic articles and research reports to provide references for policy making

《药品上市许可持有人制度下的监管能力建设与区域产业升级——长三角地区经验汇总概述》文章收录于《药品监管前沿研究（2023）》

Regulatory Capacity Building and Regional Industrial Upgrading Under the MAH System - Summary of Yangtze River Delta Region Experience was included in *Frontiers in Drug Regulation Research (2023).*

《转化医学的生态建设及投融资机遇（章节）》发表于《精准医学创新研究与产业发展报告》系列图书中

Ecosystem Development and Investment Opportunities in Translational Medicine (Selected Chapters) was Published in *Report on Precision Medicine Innovative Research and Industry Development*

中国药促会与 PharmaBoardroom 合作出版了《2024 中国医疗与生命科学回顾》专刊

PhIRDA in collaboration with PharmaBoardroom, has published the special edition *Healthcare & Life Sciences Review China 2024.*

《中国药品监管四十年变迁与思考》一文刊登于《中国药房》杂志

Forty Years of Changes and Thinking on China's Drug Regulation was published on *China Pharmacy*

《创新多元支付体系支持高值创新药物准入和落地实施研究》发表于《中国医疗保险》期刊

Research on Innovative Diverse Payment Systems Supporting the Access and Implementation of High-value Innovative Drugs was published in *China Health Insurance*

《关于我国医疗器械审评审批制度改革的思考》《WHO 监管评估体系对我国药品监管国际化的思考》文章刊登于《中国食品药品监管》杂志

Thoughts on the Reform of China's Medical Device Review and Approval System and *Overview of WHO Regulatory Assessment System and Reflection on the Internationalization of China's Drug Regulation* was published on the *China Food and Drug Administration Magazine*

PART-5

加强国际交流与合作，共话创新共赢未来

Strengthening International Exchanges and Cooperation, Sharing Innovation and Creating a Win-Win Future

积极参与国际规则制定，增强中国话语权

Actively Participate in Drafting of International Regulations, Making the Voice of China Heard

专家推荐

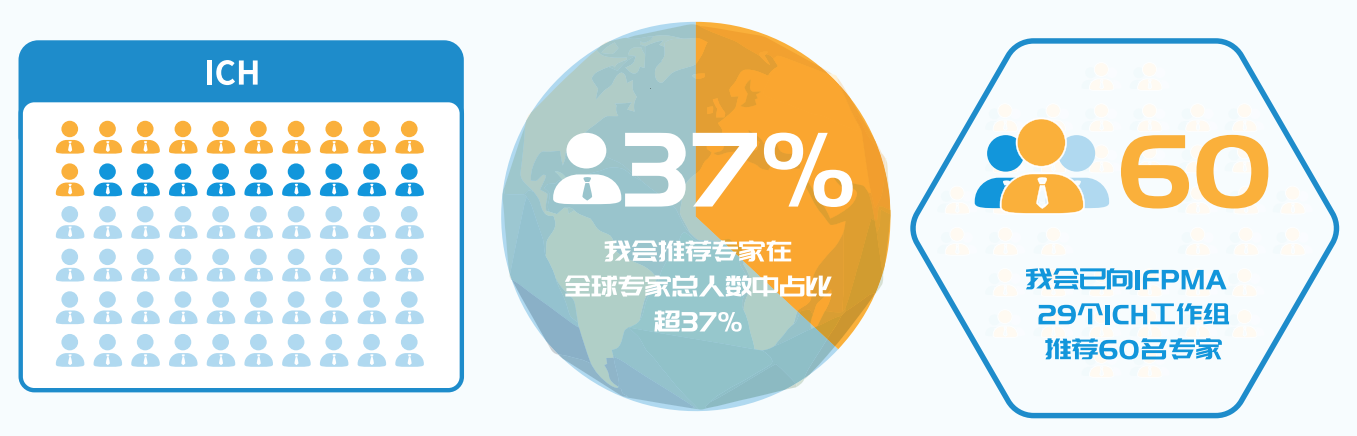
Expert Recommendation

作为国际药品制造商协会联合会（IFPMA）成员，截止 2024 年底，我会已向 IFPMA 29 个 ICH 工作组推荐 60 名专家（包括 11 名组长，9 名候补组长），我会推荐的专家在 IFPMA 全球专家总人数中占比超过 37%。

我会推荐的 130 位专家被纳入 39 个 CDE ICH 专家工作组中。

As the member of International Federation of Pharmaceutical Manufacturers Associations (IFPMA), PhIRDA has recommended 60 experts (including 11 Leads and 9 Alternates) to 29 IFPMA ICH Task Forces by the end of 2024. accounting for more than 37% of the total number of IFPMA experts around the world.

A total of 130 experts recommended by PhIRDA have been included in 39 CDE ICH Experts Working Groups.



推动 ICH 指导原则转化实施

Promote the Implementation of ICH Guidelines

受国家药品监督管理局 ICH 工作办公室委托，我会已对 71 个 ICH 指导原则征求会员单位意见建议，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。

Entrusted by the ICH Office of NMPA, PhIRDA solicited opinions from members and timely fed back industry opinions on 71 ICH Guidelines to promote the smooth implementation of ICH Guidelines in China.

中国药促会 IFPMA ICH 专家受邀参加 ICH 大会
IFPMA ICH Experts Recommended by PhIRDA Attended the ICH Assembly

IFPMA 参会代表（左一徐菊芳，右三李文斌，右六安振明）
Representatives from IFPMA (First from left: XU Jufang, third from right: LI Wenbin,
sixth from right: AN Zhenming)

2024年
6月1日至5日・日本

June 1-5,
2024 ・ Japan

IFPMA 参会代表（右一至三分别为：孟渊、安振明、李文斌）
Representatives from IFPMA (From right to left: MENG Yuan, AN Zhenming, LI Wenbin)

2024年11月
2日至6日・加拿大

November 2-6,
2024 ・ Canada

深化国际交流与合作，共建人类卫生健康共同体
Enhance International Exchange and Cooperation to Build a Community of Common Health for Mankind

中国药促会执行会长宋瑞霖会见乌兹别克斯坦卫生部副部长 Tashpulatov Farhodjon（2024 年 1 月 18 日·北京）
Executive President Song Ruilin met with Tashpulatov Farhodjon, Deputy Minister of the Ministry of Health of the Republic of Uzbekistan (January 18, 2024 · Beijing)

中国药促会执行会长宋瑞霖会见韩国制药生物协会副会长李铉禹（2024 年 6 月 20 日·上海）
Executive President Song Ruilin met with Hyunwoo Lee, Deputy President of Korea Pharmaceutical and Bio-pharma Manufacturers Association (KPBMA) (June 20, 2024 · Shanghai)

中国药促会执行会长宋瑞霖会见荷兰卫生、福利和体育部副大臣胡梓吟（2024 年 6 月 24 日·北京）
Executive President Song Ruilin met with Barbara Goezinne, Vice Minister of the Ministry of Health, Welfare and Sport of the Netherlands (June 24, 2024 · Beijing)

中国药促会执行会长宋瑞霖会见欧洲制药工业协会联合会主席 Lars Fruergaard Jørgensen（2024年9月11日·北京）
Executive President Song Ruilin met with Lars Fruergaard Jørgensen, President of the European Federation of Pharmaceutical Industries and Associations (EFPIA) (September 11, 2024 · Beijing)

双方签署合作备忘录
PhIRDA and EFPIA signed a MoU

中国药促会执行会长宋瑞霖会见澳大利亚驻成都总领事馆副总领事戴涵（2024 年 11 月 11 日・北京）
Executive President Song Ruilin met with Helen DAI, Trade and Investment Commissioner, Austrade, and Deputy Consul-General (Commercial), Australian Consulate-General, Chengdu (November 11, 2024 • Beijing)

合影留念（左：宋瑞霖 右：戴涵）
Photograph (Left: Song Ruilin, Right: Helen DAI)

中国药促会代表团访问沙特阿拉伯（2024 年 11 月 9 日 -13 日 • 利雅得）
PhIRDA Delegation visited Saudi Arabia (November 9-13, 2024 • Riyadh)

受沙特阿拉伯政府相关部门邀请，我会秘书长冯岚率中国创新药械企业代表团在沙特首都利雅得开展公务交流活动，与沙特卫生、药监、投资、采购、临床研究机构及当地药械企业开展交流座谈及实地参访。

Upon the invitation from the governments of Saudi Arabia, and led by Secretary-General Feng Lan, PhIRDA organized a delegation of Chinese innovative pharmaceutical and medical device enterprises to pay an official visit in Riyadh, conducting exchanges and site visits with departments of health, drug administration, investment, procurement, clinical research and local pharmaceutical and medical device companies.

冯岚秘书长与沙特投资部会谈发言
Secretary-General Feng Lan delivers remarks at the meeting with Ministry of Investment of Saudi Arabia (MISA)

与沙特药监局会谈合影
Group Photo with Saudi Food and Drug Authority (SFDA)

代表团峰会合影
Group Photo at the Riyadh Global Medicine Biotechnology Summit

与 KAIMRC 会谈合影
Group Photo with KAIMRC

代表团与 New Bridge Pharma 合影
Group Photo with New Bridge Pharma

中国药促会会长张抒扬、执行会长宋瑞霖会见韩国制药生物协会会长卢允宏（2024 年 11 月 30 日 • 广州）
PhIRDA Chairman Zhang Shuyang and Executive President Song Ruilin met with Yunhong NOH, President of Korea Pharmaceutical and Bio-pharma Manufacturers Association (KPBMA) (November 30, 2024 • Guangzhou)

双方签署合作备忘录
PhIRDA and KPBMA signed a MoU

PART-6

汇聚专业智慧与力量，发挥专家资源与优势

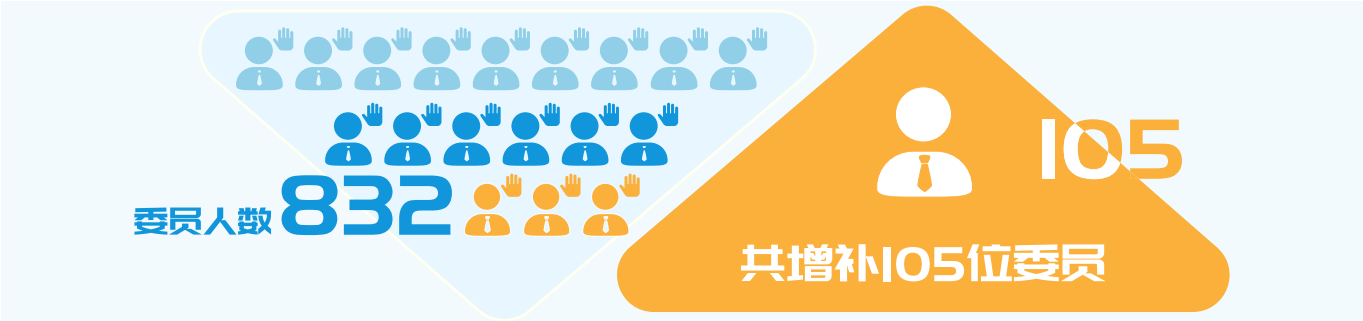
Pool Professional Wisdom and Power, Leverage Expert Resources and Advantages

充实专业委员会力量，进一步激发工作动能

Enhance the Strength of Specialty Committees, Further Stimulate Momentum for Work

2024 年度内，我会完成全部分支机构的委员增补工作。经过严格的委员推荐和遴选程序，共增补 105 位委员，其中 18 位来自 IFPMAICH 工作组成员，增补后共有委员 832 人。

In 2024, PhIRDA’s specialty committees successfully completed the supplementing of members. Following a rigorous recommendation and selection process, 105 new members were supplemented , including 18 members from IFPMA ICH Experts Working Groups. After the supplementation, the total number of committee members reached 832.



发挥专业委员会资源优势，引领行业高质量发展

Leverage the Resource Advantages of Specialty Committees to Lead the Industry’s High-Quality Development

2024 中国药促会脑神经药物临床研究专业委员会年会（2024 年 1 月 27 日 · 北京）

Annual Meeting of PhIRDA Clinical Research on Cranial Nerve Drugs Specialty Committee (January 27, 2024 · Beijing)

会议总结和探讨我国脑神经领域创新药研发临床进展及相关学科发展热点话题，聚焦未被满足的临床需求，推动源头创新的可持续发展。

The meeting summarized and discussed the clinical progress of innovative drug development in the field of cranial nerve diseases in China, as well as the latest trends in related disciplines, focusing on unmet clinical needs, promoting the sustainable development of original innovation.

第二届中国糖尿病和代谢性疾病药物器械创新研发大会（2024 年 4 月 27 日 -28 日 • 成都）
The 2nd China Innovation Conference on Diabetes, Metabolic Diseases and Medical Devices R&D (April 27-28, 2024 • Chengdu)

由中国药促会糖尿病与代谢性疾病药物临床研究专委会、药物研发专委会联合主办，四川省预防医学会内分泌代谢性疾病防控分会协办的第二届中国糖尿病和代谢性疾病药物器械创新研发大会在成都召开。以“聚力创新，价值领航”为主题，大会聚焦糖尿病及代谢性疾病领域的药械创新要点、难点，紧密围绕临床需求，深入探讨创新研发解决方案。

Co-hosted by PhIRDA Clinical Research on Diabetes and Metabolic Diseases Drugs Specialty Committee and Drug R&D Specialty Committee, and supported by Endocrine and Metabolic Disease Prevention and Control Branch of Sichuan Preventive Medicine Association, the 2nd China Innovation Conference on Diabetes, Metabolic Diseases, and Medical Devices R&D was held in Chengdu. Themed “Empower Innovation, Value Oriented”, the conference focused on the key challenges and opportunities in drug and medical device innovation for diabetes and metabolic diseases, closely aligning with clinical needs and deeply exploring innovative R&D solutions.

纪立农 中国药促会糖尿病与代谢性疾病药物临床研究专委会主任委员、北京大学人民医院内分泌科主任

Ji Linong, Chairman of PhIRDA Clinical Research on Diabetes and Metabolic Disease Drugs Specialty Committee, Director of Department of Endocrinology, Peking University People’s Hospital

鲁先平 中国药促会药物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 Drug R&D Specialty Committee, Chairman of the Board & President of Shenzhen Chipscreen Biosciences

中国生物医药出海合作与发展闭门研讨会（2024 年 5 月 7 日・深圳）
Closed-Door Symposium on China Biopharmaceutical Going Global Cooperation and Development (May 7, 2024 ・ Shenzhen)

本次研讨会由中国药促会国际创新药物监管专委会、医药企业合规专委会、科兴生物制药股份有限公司共同主办，以推动国内外药企和投资机构间的沟通和交流为目的，以中国生物医药出海的合作与发展为主题，联合中国生物医药企业领袖探讨中国生物医药出海的机遇与挑战，构建生态圈，促进在华跨国药企与中国生物医药企业及投资机构的沟通与合作。

The symposium was co-hosted by PhIRDA International Regulatory Science Specialty Committee, Ethics and Business Compliance Specialty Committee, and Sinovac Biotech, aiming to promote communication and exchange between domestic and international pharmaceutical companies and investment institutions. Themed on the cooperation and development of China’s pharmaceutical industry going global, the symposium brought together leaders of pharmaceutical enterprises to explore the opportunities and challenges of China’s pharmaceutical industry expanding overseas, focusing on building an ecosystem to foster communication and cooperation among multinational pharmaceutical companies in China, Chinese pharmaceutical enterprises and investment institutions.

2024 中国医药创新政策论坛（2024 年 6 月 21 日 • 上海）
2024 China Pharmaceutical Innovation Policy Forum (June 21, 2024 • Shanghai)

由中国药促会医药政策专委会、上海张江（集团）有限公司以及艾美达医药咨询主办的2024中国医药创新政策论坛在上海召开。论坛以“聚力创新 面向国际 共话未来”为主题，围绕“‘浦东方案’落地举措探讨”“创新支付体系”两大主题开展了报告分享与讨论。

Co-hosted by PhIRDA Medicinal Policy Specialty Committee, Shanghai Zhangjiang (Group) and iMeta Health Information Consulting, 2024 China Pharmaceutical Innovation Policy Forum was held in Shanghai. Themed “Innovate Together, Integrate into International Community, Shape the Future”, the forum focused on Implementation Plan for the Pilot Comprehensive Reform of Pudong New Area and Innovative Payment System, and KOLs delivered keynote speeches and conducted discussions.

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药师、首席专家
Hu Xin, Chairman of PhIRDA Medicinal Policy Specialty Committee, Chief Pharmacist & Chief Expert, Department of Pharmacy, Beijing Hospital

吴强 上海市浦东新区区委常委、副区长
Wu Qiang, Member of the Standing Committee of the CPC Pudong New Area Committee and Deputy District Mayor of Pudong New Area, Shanghai

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

张清 上海市药品监督管理局副局长
Zhang Qing, Deputy Director-General of Shanghai Medical Products Administration

林建宁 国家药监局南方医药经济研究所原党委书记
Lin Jianning, Former Secretary of the Party Committee of National Medical Products Administration Institute of Medical Economic

主题讨论：“浦东方案”—2024年中国创新迎来新的曙光

Panel Discussion: Implementation Plan for the Pilot Comprehensive Reform of Pudong New Area - A New Dawn for China’s Innovation in 2024

主题讨论：面向未来—共话创新、产业化、国际化

Panel Discussion: Looking Ahead - Shaping the Future through Innovation, Industrialization, Internationalization

2024 抗肿瘤药物创新研发大会暨《2023 年度中国抗肿瘤新药临床研究评述》发布会（2024 年 8 月 31 日 · 上海）
2024 Conference on the Clinical Research of Anti-tumor Innovative Drugs in Shanghai, jointly publishing the 2023 Review of Clinical Research on New Anti-tumor Drugs in China (August 31, 2024 · Shanghai)

由中国药促会抗肿瘤药物临床研究专委会、艾美达医药咨询、北京市希思科临床肿瘤研究基金会等联合主办的2024 抗肿瘤药物创新研发大会暨《2023 年度中国抗肿瘤新药临床研究评述》发布会在上海召开。大会重点围绕“抗肿瘤领域源头创新”与“新形势下抗肿瘤新药研发的挑战与出路”两大主题展开报告分享与讨论。

PhIRDA Clinical Research on Oncology Drugs Specialty Committee, Beijing CSCO Clinical Oncology Research Foundation and East Clinical Center of Oncology (ECCO) held the 2024 Conference on the Clinical Research of Anti-tumor Innovative Drugs in Shanghai, jointly publishing the *2023 Review of Clinical Research on New Anti-tumor Drugs in China.* The conference focused on Original Innovation in the Field of Anti-tumor Research and Challenges and Solutions in the Development of New Anti-tumor Drugs under the New Circumstances, and KOLs delivered keynote speeches and conducted discussions.

药械产业数智生物技术创新大会（2024 年 10 月 12 日 · 苏州）
The Pharmaceutical and Medical Device Industry Digital Intelligence and Biotechnology Innovation Conference (October 12, 2024 · Suzhou)

由中国药促会医药数字化及创新疗法专委会、创新医疗器械专委会及艾美达医药咨询联合主办的药械产业数智生物技术创新大会在苏州举行。本届大会聚焦药械产业交叉学科新兴技术的转化与应用等主题展开交流与讨论。

The Pharmaceutical and Medical Device Industry Digital Intelligence and Biotechnology Innovation Conference, co-hosted by PhIRDA Digital Medicine and Innovative Therapy Specialty Committee and Innovative Medical Devices Specialty Committee, was held in Suzhou. The conference focused on the transformation and application of emerging interdisciplinary technologies in the pharmaceutical and medical device industries.

脑神经药物临床研究专委会学术年会暨天坛肿瘤规范化诊疗暨脑胶质瘤非手术治疗进展学习班（2024年11月24日·北京）
Organized by PhIRDA Clinical Research on Cranial Nerve Drugs Specialty Committee, the Academic Annual Conference and the Workshop on Standardized Diagnosis and Treatment of Tian Tan Oncology and Non-Surgical Treatment Advances in Brain Gliomas (November 24, 2024 · Beijing)

《关于完善港股通相关政策的倡议》（2024 年 12 月）
The Proposal on Improving the Policies Related to the Hong Kong Stock Connect (December, 2024)

中国药促会药物研发、医药创新投资专委会组织生物科技公司、投资机构和服务机构等香港资本市场各参与方代表围绕港股通相关制度进行了研讨与交流，形成《关于完善港股通相关政策的倡议》报送中国证券监督管理委员会。

PhIRDA Pharmaceutical Innovation Investment Specialty Committee and Drug R&D Specialty Committee organized representatives from biotechnology companies, investment institutes, service institutions, and other stakeholders to conduct research and exchanges on the Hong Kong Stock Connect, and submitted the *Proposal on Improving the Policies Related to the Hong Kong Stock Connect* to the China Securities Regulatory Commission.


中国医药创新促进会

药促字〔2024〕44号

关于完善港股通相关政策的倡议

中国证券监督管理委员会：

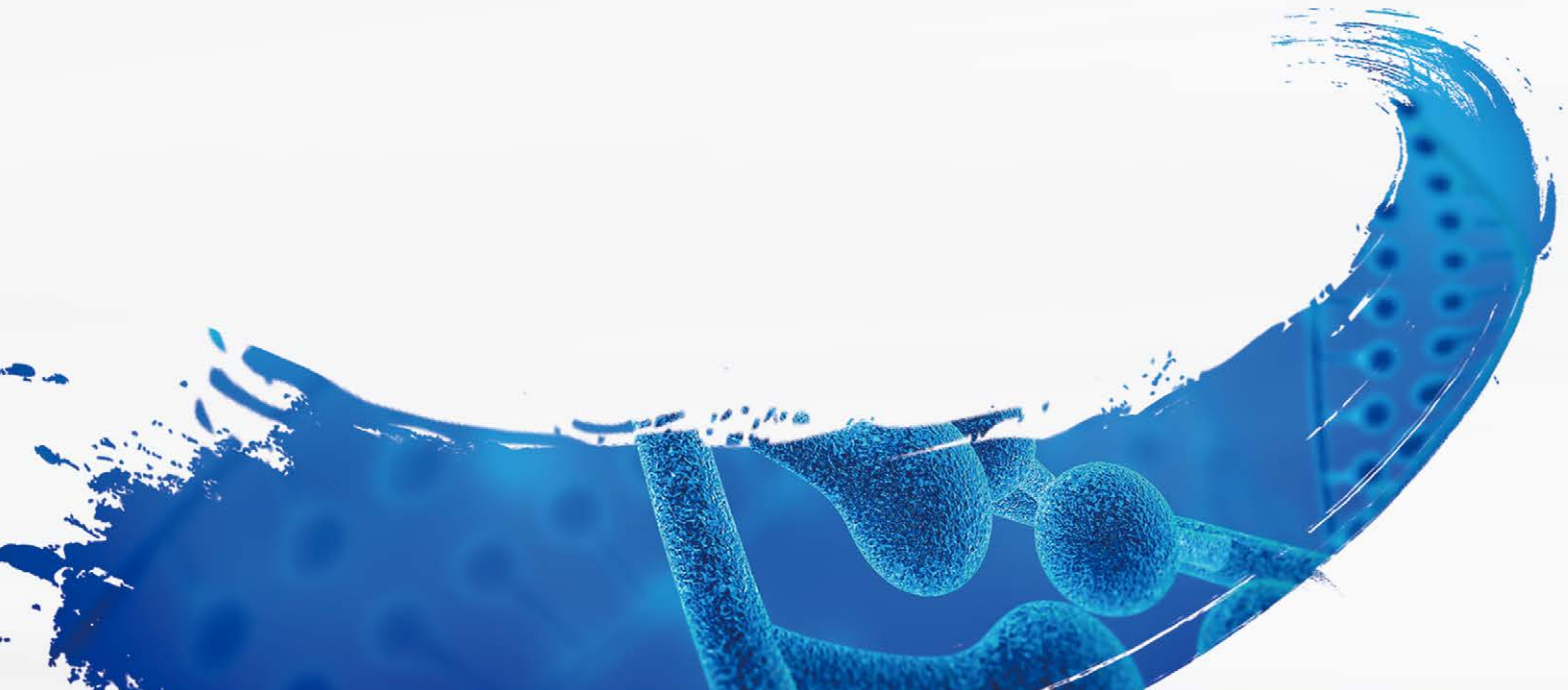
2014年11月17日，沪港通正式启动，现场看内地与香港证券市场开启了互联互通的新时代；近年来，港交所推出《上市规则》第“18A”和“18C”章节，上海证券交易所科创板开板，为没有收入的生物科技公司提供了特殊的上市条件和更新型的融资渠道，两地资本市场适应国家先导产业发展需求，为金融服务全面支持科技创新迈出了重要一步。风雨十载，在监管和市场各主体的共同努力下，两地已构建起覆盖股票、债券、资管和利率互换衍生产品在内的全方位互联互通体系。港股通作为连接内地与全球资本的重要桥梁，为巩固香港全球主要金融中心地位和支持创新主体高质量发展发挥了重要作用。特别是在“18A”和“18C”章节推出后，港股通更为医药及人工智能领域交叉融合创新提供了坚

大事记

（2024 年 1 月 -2024 年 12 月）

Remarkable Events

(January, 2024 - December, 2024)



中国医药创新促进会大事记（2024 年）

1 月 Jan.

1 月 3 日

我会召开“中国创新药出海技术路径研究”结题会。

1 月 4 日

我会召开“中国创新医疗器械审评制度改革研究企业座谈会”。

1 月 10 日

我会受邀参加北京市卫生健康委“第二批研究型病房示范建设工作调度会”。

1 月 11 日

我会秘书长冯岚带队，走访会员单位北京科信必成医药科技发展有限公司。

1 月 18 日

我会执行会长宋瑞霖会见乌兹别克斯坦卫生部副部长 Tashpulatov Farhodjon。

1 月 27 日

我会脑神经药物临床研究专业委员会主办的年会活动在北京顺利召开。

1 月 29 日

我会受邀参加北京市卫生健康委“第三批研究型病房示范建设工作调度会”。

2 月 Feb.

2 月 22 日

我会“第十一届理事会第五次会议”在北京召开，北京协和医院院长张抒扬当选我会 2024 年度会长。会议表决通过了《关于成立换届工作领导小组的议案》。

礼进生物医药科技（上海）有限公司、映恩生物制药（苏州）有限公司、维昇药业（上海）有限公司加入我会。

2 月 23 日

我会向国家医疗保障局医药价格和招标采购司提交《关于建立新上市化学药品首发价格形成机制鼓励高质量创新的通知（征求意见稿）》的意见和建议。

2 月 29 日

我会执行会长宋瑞霖受邀参加中国罕见病联盟主办的“第十七届国际罕见病日系列活动”，并作主旨报告。

3 月 Mar.

3 月 14 日

我会执行会长宋瑞霖带队拜会国家医疗保障局相关负责领导，就新上市化学药品首发定价机制进行交流并提出建议。

3 月 16 日

我会执行会长宋瑞霖，副会长孙飘扬、李燕以及多家会员单位代表当选中国国际经济交流中心第三届理事会理事。

3 月 19 日

我会执行会长宋瑞霖带队，走访会员单位上海礼邦医药科技有限公司和维昇药业（上海）有限公司。

我会在上海组织召开“会员单位交流座谈会”。

3 月 22 日

我会执行会长宋瑞霖，副会长刘殿波、吴晓滨等，以及部分专家及会员代表受邀参加由中国国际经济交流中心和中国外商投资企业协会共同主办的“第五届国际创新医药大会”。

3 月 27 日

我会秘书长冯岚带队，走访会员单位北京泰德制药股份有限公司和悦康药业集团股份有限公司。

4 月 Apr.

4 月 2 日

我会向中国农工民主党中央委员会提交《关于开展创新药发展有关支持政策调研考察建议报告》。

4 月 12 日

我会收到国家发展改革委体改司来函协助开展新质生产力专题研究，并递交《关于打通生物医药创新全链条堵点卡点 促进新质生产力发展的研究》报告。

4 月 23 日

我会线上参加了第十三届亚洲制药组织合作会议（APAC）大会。会上发布了我会及会员单位参与撰写的《2024 年亚洲医药市场与监管》报告。

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”课题中期会。

4 月 26 日

我会执行会长宋瑞霖带队，走访我会理事单位科伦药业创新药物研发平台——四川科伦博泰生物医药股份有限公司。

我会受邀参加国家药监局政法司召开的“《医疗器械管理法》行业协会学会和专家座谈会”。

4 月 27 日—28 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、药物研发专业委员会联合主办的“第二届中国糖尿病和代谢性疾病药物器械创新研发大会”在成都召开。

4 月 28 日

我会受邀参加国家药监局组织召开的“深化药监改革促进医药产业高质量发展专题座谈会”。

5 月 May

5 月 7 日

由中国医药创新促进会国际创新药物监管专业委员会、医药企业合规专业委员会以及科兴生物制药股份有限公司共同主办的“中国生物医药出海合作与发展闭门研讨会”在深圳召开。

5 月 11 日

国家卫生健康委药政司司长张锋一行来我会开展国家药物政策专题座谈调研。

5 月 16 日—17 日

由香港特区政府和香港贸发局共同主办的第四届“亚洲医疗健康高峰论坛”在香港举行，作为本届论坛的支持单位，我会深度参与了论坛筹备工作。

5 月 21 日

我会执行会长宋瑞霖受邀参加由中国国际经济交流中心举办的“完善药品监管政策”座谈会。

5 月 23 日

我会召开“中国创新医疗器械审评制度改革研究”企业座谈会。

5 月 29 日

我会执行会长宋瑞霖带队，走访会员单位华东医药股份有限公司。

5 月 30 日

“中国医药创新促进会 2024 年会长会议扩大会议暨换届工作领导小组工作会议”在杭州召开。

由我会和杭州市人民政府共同指导的“杭州生物医药产业座谈会”在杭州召开。

5 月 31 日

我会执行会长宋瑞霖带队，走访会员单位上海银诺医药技术有限公司。

6 月
Jun.

6 月 1 日—5 日
ICH 大会在日本福冈召开，我会推荐的 IFPMA ICH 专家现场参会。

6 月 4 日—6 日
我会执行会长宋瑞霖受邀列席全国政协十四届常委会第七次会议。

6 月 14 日
我会执行会长宋瑞霖受邀参加上海市药品监管局举办的 2024 年第二期“药讲堂”活动，并作主题报告。

6 月 19 日
我会成功推荐三位专家加入 IFPMA ICH S13 工作组，参与起草该指导原则的概念性文件及相关工作。

6 月 20 日
我会执行会长宋瑞霖会见韩国制药生物协会（KPBMA）副会长李铉禹一行。

我会召开 2024 年联络秘书工作会议。

我会召开“参照药遴选方法学共识项目”课题结题会。

6 月 21 日
由我会和上海市浦东新区人民政府指导，中国医药创新促进会医药政策专业委员会、上海张江（集团）有限公司以及艾美达医药咨询联合主办的“2024 中国医药创新政策论坛”在上海召开。

6 月 24 日
我会执行会长宋瑞霖、副会长吴晓滨会见荷兰卫生、福利和体育部医疗服务副大臣胡梓吟一行。

6 月 25 日
我会执行会长宋瑞霖会见“知行中国”项目访华学者 Daniel Jimenez 和 Srey Ram Kuy。

6 月 27 日
由中国医药创新促进会医药政策、药物研发和国际创新药物监管专业委员会共同支持的“创新药全球开发策略与路径交流会”在苏州召开。

我会向上海市浦东新区人民政府递交《关于推动“浦东方案”落地的建议举措》。

6 月 28 日
财政部国际经济关系司副司长杨剑敏一行来我会开展专题调研。

7 月
Jul.

7 月 2 日
我会党支部组织党员、积极分子前往中国共产党历史展览馆参观学习。

7 月 4 日
我会召开“临床试验相关会议方案研讨会”。

我会执行会长宋瑞霖受邀参加由中国国际经济交流中心主办的“第八届全球智库峰会”，并参与讨论。

海思科医药集团股份有限公司、长春金赛药业有限责任公司、北京高博医疗科技集团有限公司、上海璎黎药业有限公司、维亚臻生物技术（苏州）有限公司、海森生物医药有限公司、上海济煜医药科技有限公司加入我会。

7 月 10 日
我会受邀参加由财政部国际关系司召开的“创新药产业发展”座谈会。

7 月 17 日
我会受邀参加由中国国际经济交流中心主办的“完善我国医保目录谈判制度”座谈会。

7 月 25 日
我会在烟台召开“医药创新与临床试验大会相关方案专家研讨会”。

7 月 31 日
我会召开“深化基因测序技术监管改革 培育新质生产力”座谈会。

8 月 Aug.

8 月 6 日

我会执行会长宋瑞霖带队，拜会国家药监局医疗器械技术审评中心相关负责领导，就“进一步提升审评能力与效率、建立药械创新协同机制”等话题展开交流并提出建议。

8 月 13 日

我会执行会长宋瑞霖带队，拜会国家药监局器械注册司相关负责领导，就“医疗器械产品风险界定、优化监管政策引领医疗器械有效创新”等话题展开交流并提出建议。

8 月 14 日

我会成功推荐两位专家加入 IFPMA ICH M7 分工作组，参与起草该指导原则的概念性文件及相关工作。

8 月 16 日

我会受商务部外贸司委托，就我国生物医药产品贸易情况及政策监管障碍提交《关于我国医药产业创新出海现状问题及建议》的报告。

8 月 17 日

我会课题研究成果《WHO 监管评估体系概况及对我国药品监管国际化的思考》在《中国食品药品监管》杂志发表。

8 月 27 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”课题结题会。

8 月 31 日

由中国医药创新促进会抗肿瘤药物临床研究专业委员会、艾美达医药咨询、北京市希思科临床肿瘤研究基金会以及东方临床肿瘤研究中心联合主办的“2024 年抗肿瘤药物创新研发大会暨《2023 年度中国抗肿瘤新药临床研究评述》发布会”在上海召开。

9 月 Sep.

9 月 2 日

我会秘书长冯岚参加由国家药品监督管理局召开的“《中华人民共和国药品管理法》颁布四十周年座谈会”。

9 月 6 日—7 日

由我会、合肥综合性国家科学中心大健康研究院、合肥综合性国家科学中心办公室、安徽省生命健康产业推进组办公室等机构共同主办的“第二届合肥生物医药创新与产业大会”在合肥召开。

9 月 11 日

我会执行会长宋瑞霖会见欧洲制药工业协会联合会主席 Lars Fruergaard Jørgensen 一行，双方正式签署了合作备忘录，将进一步深化合作，推动会员单位在中国、欧洲以及全球范围内的交流合作。

国家发改委价格成本和认证中心及药品审评中心相关领导莅临我会，开展药品注册收费改革专题调研并召开企业座谈会。

9 月 12 日

我会党支部与华润双鹤党委开展“传承红色基因、共创医药未来”联合主题党日活动。

9 月 18 日

我会召开“中国创新医疗器械审评制度改革研究”课题结题会。

9 月 19 日

我会成功推荐十位专家加入国家药监局药审中心 ICH Q6(R1) 议题国内专家工作组。

9 月 26 日

我会向国家药监局提交关于《中华人民共和国医疗器械管理法（草案征求意见稿）》的反馈意见。

9 月 27 日

齐济（苏州）创业投资有限公司和香港维健医药集团有限公司加入我会。

9 月 29 日

我会召开“国际化背景下创新药定价机制研究”课题开题会。

10 月
Oct.

10 月 12 日

由我会医药数字化及创新疗法专业委员会和创新医疗器械专业委员会联合主办的“药械产业数智生物技术创新大会”在苏州召开。

中国医药创新促进会（吴中）产业转化基地落地苏州。

10 月 18 日

我会分支机构委员增补工作顺利完成。

10 月 19 日

由我会与中国罕见病联盟等单位联合主办的“2024 中国罕见病大会”在北京召开。

10 月 21 日

我会向国家市场监督管理总局提交关于《医药企业防范商业贿赂风险合规指引（征求意见稿）》的反馈建议。

10 月 22 日

我会执行会长宋瑞霖受邀担任香港生物医药创新协会（HKBMIA）荣誉会长。

10 月 25 日

我会执行会长宋瑞霖受邀参加“2024 国际生物医药产业创新北京论坛”，并作主旨报告。

我会秘书长冯岚带队，走访会员单位武汉禾元生物科技股份有限公司。

10 月 26 日—27 日

由我会与武汉东湖新技术开发区管理委员会共同指导的第二届溶瘤病毒创新与合作大会在武汉召开。

10 月 27 日

由我会、浙江省医药行业协会以及贝达药业共同主办的“贝耀东方——创新药发展论坛”在杭州召开。

我会与北京药学会、中国外商投资企业协会药品研制和开发工作委员会共同研究形成的《北京市药物临床试验合同共识（2024 年）》在京发布。

11 月
Nov.

11 月 1 日

我会执行会长宋瑞霖受邀参加国家发展和改革委员会体制改革综合司组织的推动创新药改革试点方案专题座谈会。

11 月 2 日—6 日

我会推荐的 IFPMA ICH 专家现场参加在加拿大蒙特利尔召开的 ICH 大会。

11 月 5 日

我会执行会长宋瑞霖会见美国丹纳赫集团全球执行副总裁兼思拓凡全球总裁 Chris Riley。

11 月 7 日

我会与中国临床肿瘤学会、北京市希思科临床肿瘤学研究基金会、中再寿险、镁信健康在第七届进博会签署战略合作协议。

11 月 8 日

我会协助国家药监局药审中心开展 2024 年度顾客满意度调查工作。

11 月 9 日—13 日

受沙特阿拉伯政府相关部门邀请，由冯岚秘书长带队，我会组织 10 家会员单位赴沙特参观考察，与沙特卫生、药监、投资、采购、临床研究机构及当地药械企业开展交流座谈及实地参访。

11 月 11 日

我会执行会长宋瑞霖会见澳大利亚驻成都总领事馆副总领事（商务）及澳大利亚贸易投资委员会商务投资专员戴涵。

11 月 12 日

我会受北京市卫健委委托，组织专家参加“人工智能赋能药物研发专家座谈会”。

11 月 21 日

我会受国家卫生健康委国际司邀请，参加“深化医药创新与健康产业国际合作专题研讨会”。

11 月 22 日

我会召开“研究型病房建设评估指标体系”专家研讨会。

11 月 24 日

我会“脑神经药物临床研究专委会学术年会暨天坛肿瘤规范化诊疗暨脑胶质瘤非手术治疗进展学习班”在北京召开。

11 月 25 日

我会受国家发改委一带一路建设促进中心邀请，参加“2024 年度健康丝绸之路建设形式专家座谈会”。

11 月 30 日—12 月 1 日

由中国国际经济交流中心指导，我会联合香港交易所和艾美达医药咨询共同主办的“第九届医药创新与投资大会”在广州召开。

11 月 30 日

我会会长张抒扬和执行会长宋瑞霖会见韩国制药生物协会会长卢允宏一行，双方正式签署合作备忘录，将进一步推动中韩两国医药产业界合作交流。

12 月
Dec.

12 月 2 日

民政部发布《2024 年全国性社会组织评估等级（第二批）公告》，我会再次获评 4A 级全国性社会组织。

12 月 3 日

由我会主办的“2024 首届‘湾区之星’生物医药源头创新大会”在深圳召开。

12 月 10 日

我会与中国国际经济交流中心共同组织召开“加快商业医疗保险发展座谈会”。

12 月 12 日

我会向中国证券监督管理委员会报送《关于完善港股通相关政策的倡议》。

12 月 13 日

我会执行会长宋瑞霖受邀参加全国政协第二十七次双周协商座谈会，围绕“加快推进创新药物和高端医疗设备的研发与临床应用”协商议政。

我会受财政部国际经济关系司委托，组织会员企业参加“对英投资合作企业座谈会”。

12 月 18 日

我会执行会长宋瑞霖受邀参加国家发改委创新中心组织召开的“生物经济专题研究会”。

12 月 20 日

我会受国家药监局药审中心委托，组织会员企业参加的“鼓励和促进罕见病药物创新研发交流会”。

12 月 30 日

我会向国家发改委体改司提交《关于进一步发展商业医疗保险的建议意见》。

南京传奇生物科技有限公司、武汉朗来科技发展有限公司、兰胜供应链管理（上海）有限公司加入我会。

Remarkable Events of PhIRDA (2024)

January

January 3

PhIRDA held the project closure meeting of Study on the Technical Pathway for China's Innovative Drugs Going Global.

January 4

PhIRDA held the Enterprise Symposium on the Reform of the Clinical Review System for China's Innovative Medical Devices.

January 10

PhIRDA was invited to attend the scheduling meeting for the Second Batch of Demonstration Units for Research-oriented Ward Construction hosted by the Beijing Municipal Health Commission.

January 11

Secretary-General Feng Lan led a PhIRDA delegation to visit member-Beijing CoSci Med-tech.

January 18

Executive President Song Ruilin met with Tashpulatov Farhodjon, Deputy Minister of the Ministry of Health of the Republic of Uzbekistan.

January 27

PhIRDA Clinical Research on Cranial Nerve Drugs Specialty Committee successfully held its annual meeting in Beijing.

January 29

PhIRDA was invited to attend the scheduling meeting for the Third Batch of Demonstration Units for Research-oriented Ward Construction hosted by the Beijing Municipal Health Commission.

February

February 22

PhIRDA held the Fifth Meeting of the 11th Board of Directors in Beijing, during which Zhang Shuyang, President of Peking Union Medical College Hospital, was elected as 2024 PhIRDA Chairman. The meeting passed the *Proposal to Establish the Leading Group for the Work of General Election.*

Lyvgen Biopharma (Shanghai), Duality Biologics (Suzhou), and Visen Pharmaceuticals (shanghai) joined PhIRDA.

February 23

PhIRDA submitted the suggestions on the Establishment of a Pricing Mechanism for Newly Launched Chemical Drugs to Encourage High-Quality Innovation (Draft for Comments) to the Department of Drug Prices and Procurement of National Healthcare Security Administration.

February 29

Executive President Song Ruilin was invited to attend the Series of Activities of 17th International Rare Disease Day hosted by China Alliance for Rare Diseases and delivered a keynote speech.

March

March 14

Executive President Song Ruilin led a delegation to meet with relevant officials from the National Healthcare Security Administration to discuss the new pricing mechanism for newly launched chemical drugs and provided suggestions.

March 16

Executive President Song Ruilin, Vice Presidents Sun Piaoyang, Li Yan, and several representatives from members were elected as the Board of Directors of the Third Council for the China Center for International Economic Exchanges.

March 19

Executive President Song Ruilin led a PhIRDA delegation to visit members, Alebund Pharmaceuticals and Visen pharmaceuticals (shanghai).

PhIRDA organized a Symposium for PhIRDA Members in Shanghai.

March 22

Executive President Song Ruilin, Vice Presidents Liu Dianbo, Wu Xiaobin and other experts and representatives from PhIRDA members were invited to attend the 5th International Pharmaceutical Innovation Forum jointly organized by the China Center for International Economic Exchanges and the China Association of Enterprises with Foreign Investment.

March 27

Secretary-General Feng Lan led a PhIRDA delegation to visit members, Beijing Tide Pharmaceutical and Youcare Pharmaceutical Group.

April

April 2

PhIRDA submitted the *Report on Supporting Policies for the Development of Innovative Drugs* to the Central Committee of Chinese Peasants and Workers Democratic Party.

April 12

Entrusted by National Development and Reform Commission to assist in conduct a monographic study on new quality productive forces, PhIRDA submitted the report titled *Research on Addressing Blockages and Bottlenecks in the Full Innovation Chain of Biopharmaceuticals to Promote New Quality Productive Forces.*

April 23

PhIRDA attended the 13th Asia Pharmaceutical Organization Cooperation Conference (APAC) online. The *Pharmaceutical Market & Regulatory Environment in Asia (PMRE) 2024,* drafted by PhIRDA and revised by its members, was released in the conference.

PhIRDA held the mid-term project meeting of Research on the Exploration of the Innovative Payment System Based on Patients Payment and Medical Insurance Payment.

April 26

Executive President Song Ruilin led a PhIRDA delegation to visit member, Sichuan Kelun -Biotech Biopharmaceutical Co., Ltd.

PhIRDA was invited to attend the Symposium on *Medical Device Administration Law* for Industry Associations and Experts held by the National Medical Products Administration (NMPA).

April 27-28

PhIRDA Clinical Research on Diabetes and Metabolic Diseases Drugs Specialty Committee and Drug R&D Specialty Committee co-hosted the 2nd China Innovation Conference on Diabetes, Metabolic Diseases and Medical Devices R&D in Chengdu.

April 28

PhIRDA was invited to attend the Symposium on Deepening Drug Regulatory Reform to Promote High-Quality Development of the Pharmaceutical Industry organized by NMPA.

May

May 7

PhIRDA International Regulatory Science Specialty Committee, Ethics and Business Compliance Specialty Committee and Sinovac Biotech co-hosted Closed-Door Symposium on China Biopharmaceutical Going Global Cooperation and Development in Shenzhen.

May 11

Zhang Feng, Director of the Drug Administration Department of the National Health Commission, led an inspection group to visit PhIRDA to conduct a symposium on national drug policies.

May 16-17

The 4th Asia Summit on Global Health, co-hosted by HKSAR Government and the Hong Kong Trade Development Council, was held in Hong Kong. As a global partner, PhIRDA deeply engaged in forum preparations.

May 21

Executive President Song Ruilin was invited to attend the Symposium on Improvement of Drug Regulatory Policies hosted by China Center for International Economic Exchanges.

May 23

PhIRDA held the enterprise symposium on the Reform in China’s Review and Approval System for Innovative Medical Devices.

May 29

Executive President Song Ruilin led a PhIRDA delegation to visit member, Huadong Medicine.

May 30

2024 PhIRDA President Board Meeting and Leading Group for the Work of General Election was held in Hangzhou.

Hangzhou Biopharmaceutical Industry Symposium, guided by PhIRDA and the Hangzhou Municipal People’s Government, was held in Hangzhou.

May 31

Executive President Song Ruilin led a PhIRDA delegation to visit member, Shanghai Innogen Pharmaceutical Technology.

June

June 1-5

The ICH Assembly was held in Fukuoka, Japan. Several IFPMA ICH experts recommended by PhIRDA attended the meeting.

June 4-6

Executive President Song Ruilin was invited to attend the 7th Meeting of the Standing Committee of the 14th National Committee of the Chinese People's Political Consultative Conference.

June 14

Executive President Song Ruilin was invited to attend 2024 the Second Lectures on " Pharmaceutical Industry" event organized by Shanghai Medical Products Administration, and addressed a keynote speech.

June 19

PhIRDA successfully nominated three experts to IFPMA ICH S13 Expert Working Group and participate in drafting the Concept Paper and related work for the guideline.

June 20

Executive President Song Ruilin met with Hyunwoo Lee, Deputy President of Korea Pharmaceutical and Bio-pharma Manufacturers Association (KPBMA).

PhIRDA held 2023 Annual Contact Representatives Meeting.

PhIRDA held the project closure meeting of Consensus on Reference Drug Selection Methodology.

June 21

2024 China Pharmaceutical Innovation Policy Forum was held in Shanghai, guided by PhIRDA and the Shanghai Pudong New Area People’s Government, and co-hosted by PhIRDA Medicinal Policy Specialty Committee, Shanghai Zhangjiang (Group) and iMeta Health Information Consulting.

June 24

Executive President Song Ruilin and Vice President Wu Xiaobin met with Barbara Goezinne, Vice Minister of the Ministry of Health, Welfare and Sport of the Netherlands.

June 25

Executive President Song Ruilin met with visiting scholars Daniel Jimenez and Srey Ram Kuy from the "Zhi-Xing China".

June 27

The Seminar on Global Development Strategy and Pathway for Innovative Drugs, co-organized by PhIRDA Specialty Committees of Medicinal Policy, Drug R&D, and International Regulatory Science, was held in Suzhou.

PhIRDA submitted Suggestions and Measures for Promoting the Implementation of the Pudong New Area's pilot comprehensive reform to the Shanghai Pudong New Area People’s Government.

June 28

Yang Jianmin, Deputy Director of the department of International Economic and Financial Cooperation of the Ministry of Finance, led an inspection group to visited PhIRDA.

July

July 2

PhIRDA Party Branch organized members and activists to visit the Museum of the Communist Party of China.

July 4

PhIRDA held the Seminar on Related Clinical Trial Programs.

Executive President Song Ruilin was invited to attend the 8th Global Think Tank Summit hosted by the China Center for International Economic Exchanges and participated in the discussion.

Haisco Pharmaceutical Group, Changchun GeneScience Pharmaceuticals, GoBroad Healthcare Group, Shanghai Yingli Pharmaceutical, Visirna Therapeutics, Hasten Biopharmaceutical and Shanghai Jemincare Pharmaceutical joined PhIRDA.

July 10

PhIRDA was invited to attend the Symposium on the Industry Development of Innovative Drugs held by the Department of International Economic Affairs, Ministry of Finance.

July 17

PhIRDA was invited to attend the Symposium on Improving Negotiation System of NDRL in China hosted by the China Center for International Economic Exchanges.

July 25

PhIRDA held an Expert Seminar on Proposals Related to the Pharmaceutical Innovation and Clinical Trials Conference in Yantai, Shandong Province.

July 31

PhIRDA hosted the Symposium on Deepening Regulatory Reforms on Gene Sequencing Technology to Foster New Productivity.

August

August 6

Executive President Song Ruilin led a delegation to meet with relevant leaders from Center for Medical Device Evaluation of NMPA. They discussed topics including improvement of review capabilities and efficiency, establishment of a collaborative mechanism for drug and medical device innovation, and provided suggestions.

August 13

Executive President Song Ruilin led a delegation to meet with relevant leaders from the Department of Medical Device Registration of NMPA. They discussed topics including defining risks of medical device products and optimizing regulatory policies to guide effective innovation in medical devices, and provided suggestions.

August 14

PhIRDA successfully nominated two experts to join the IFPMA ICH M7 Sub-Group, participating in drafting the Concept Paper and related work for the guideline.

August 16

Entrusted by the Department of Foreign Trade, Ministry of Commerce, PhIRDA submitted a report titled *Current Status and Suggestions on the Innovation of China's Pharmaceutical Industry Going Global,* addressing the trade situation and policy and regulatory obstacles of China's biopharmaceutical products.

August 17

PhIRDA's research paper titled Overview of WHO Regulatory Assessment System and Reflection on the Internationalization of China's Drug Regulation was published in the journal China Food and Drug Administration Magazine.

August 27

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

August 31

PhIRDA Clinical Research on Oncology Drugs Specialty Committee, Beijing CSCO Clinical Oncology Research Foundation and East Clinical Center of Oncology (ECCO) held the 2024 Conference on the Clinical Research of Anti-tumor Innovative Drugs in Shanghai, jointly publishing the *2023 Review of Clinical Research on New Anti-tumor Drugs in China*.

September

September 2

Secretary-General Feng Lan attended the Symposium on the 40th Anniversary of the Implementation of *the Drug Administration Law of the People's Republic of China* organized by NMPA.

September 6-7

The 2nd Hefei Biopharmaceutical Innovation & Industry Conference, co-hosted by PhIRDA, the Institute of Health and Medicine, the Office of Hefei Comprehensive National Science Center and Office of the Anhui Provincial Life and Health Industry Promotion Group, was held in Hefei.

September 11

Executive President Song Ruilin met with Lars Fruergaard Jørgensen, President of the European Federation of Pharmaceutical Industries and Associations (EFPIA). The two parties officially signed a Memorandum of Understanding to further deepen global cooperation and promote exchanges among members in China and Europe.

Senior officials from the Center for Price Cost Investigation and Authentication, National Development and Reform Commission and the Center for Drug Evaluation visited PhIRDA, conducting a corporate symposium and a special research on drug registration fee reform.

September 12

PhIRDA's Party Branch and the Party Committee of China Resources Double-Crane Pharmaceutical held a joint themed Party Day event titled "Inheriting Red Genes, Creating a Better Pharmaceutical Future Together."

September 18

PhIRDA held a project closure meeting of Reform in China's Review and Approval System for Innovative Medical Devices.

September 19

PhIRDA successfully nominated ten experts to join the CDE ICH Q6(R1) Expert Working Group.

September 26

PhIRDA submitted suggestions to the NMPA regarding the *Medical Device Administration Law of the People's Republic of China (Draft for Comments)*.

September 27

TTM (Suzhou) Venture Capital and Hongkong Winhealth Pharma Group joined PhIRDA.

September 29

PhIRDA held a project kick-off meeting for the Research on Pricing Mechanisms for Innovative Drugs in the Context of Internationalization.

October

October 12

The Pharmaceutical and Medical Device Industry Digital Intelligence and Biotechnology Innovation Conference, jointly hosted by PhIRDA Digital Medicine and Innovative Therapy Specialty Committee and Innovative Medical Devices Specialty Committee, was held in Suzhou.

PhIRDA Industry Transformation Base (Wuzhong) was established in Suzhou.

October 18

The work of supplementing members for PhIRDA's specialty committees was successfully completed.

October 19

2024 China Conference on Rare Diseases, co-hosted by PhIRDA and China Alliance for Rare Diseases (CARD), was held in Beijing.

October 21

PhIRDA submitted the suggestions and comments on the Guidelines for Pharmaceutical Enterprises to Prevent Com-

mercial Bribery Risks and Ensure Compliance (Draft for Comments) to the State Administration for Market Regulation.

October 22

Executive President Song Ruilin has been invited to serve as Honorary Chairman of HK Bio-Med Innotech Association (HKBMIA).

October 25

Executive President Song Ruilin was invited to attend the 2024 International BioMedical Industry Innovation Conference Beijing Forum, and addressed a keynote speech.

Secretary-General Feng Lan led a PhIRDA delegation to visit Wuhan Healthgen Biotech.

October 26-27

The Second Interdisciplinary Oncolytic Virotherapy Innovation Convention, jointly guided by PhIRDA and Administrative Committee of Wuhan East Lake High-tech Development Zone, was held in Wuhan.

October 27

The Bright East-Transforming Therapeutics Advancement Forum, jointly hosted by PhIRDA, Zhejiang Pharmaceutical Industry Association, and Betta Pharmaceuticals, was held in Hangzhou.

The *Beijing Consensus on Clinical Trial Contracts for Drugs (2024),* jointly developed by PhIRDA, Beijing Pharmaceutical Association and RDPAC, was released in Beijing.

November 1

Executive President Song Ruilin was invited to attend the Symposium on the Pilot Program for Promoting Innovative Drug Reform organized by the Department of Comprehensive System Reform, National Development and Reform Commission (NDRC).

November 2-6

IFPMA ICH experts nominated by PhIRDA participated in the ICH Assembly held in Montreal, Canada.

November 5

Executive President Song Ruilin met with Chris Riley, Executive Vice President, Biotechnology Group and CEO, Cytiva.

November 7

PhIRDA signed a strategic cooperation agreement with the Chinese Society of Clinical Oncology, Beijing CSCO Clinical Oncology Research Foundation, China Life Reinsurance, and MediTrust Health at the 7th China International Import Expo (CIIE).

November 8

PhIRDA assisted the Center for Drug Evaluation of NMPA in conducting the 2024 Satisfaction Survey.

November 9-13

Upon the invitation from the departments of the Saudi Arabian government, and led by Secretary-General Feng Lan, PhIRDA organized a delegation of 10 members to visit Saudi Arabia. The delegation engaged in exchange discussions and site visits with Saudi health, drug regulatory, investment, procurement, clinical research institutions, and local pharmaceutical and medical device companies.

November 11

Executive President Song Ruilin met with Helen DAI, Trade and Investment Commissioner, Austrade, and Deputy Consul-General (Commercial), Australian Consulate-General, Chengdu.

November 12

Entrusted by the Beijing Municipal Health Commission, PhIRDA organized experts to attend the Experts Symposium on AI Empowering Drug Research and Development.

November 21

Upon the invitation from the National Health Commission of the People's Republic of China, PhIRDA participated in the Seminar on Deepening International Cooperation in Pharmaceutical Innovation and Health Industry.

November 22

PhIRDA held an Expert Seminar on the Evaluation Index System for Research-Oriented Ward Construction.

November 24

The PhIRDA Clinical Research on Cranial Nerve Drugs Specialty Committee Academic Annual Conference and the Learning Workshop on Standardized Diagnosis and Treatment of Tian

Tan Oncology and Non-Surgical Treatment Advances in Brain Gliomas was held in Beijing.

November 25

Upon the invitation from the Belt and Road Center of National Development and Reform Commission (NDRC), PhIRDA attended the 2024 Symposium on the Building of a Health Silk Road.

November 30- December 1

The 2024 China BioMed Innovation and Investment Conference, guided by the China Center for International Economic Exchanges, jointly hosted by PhIRDA, HKEX and iMeta Health Information Consulting, was held in Guangzhou.

November 30

PhIRDA Chairman Zhang Shuyang and Executive President Song Ruilin met with Yunhong NOH, President of Korea Pharmaceutical and Bio-pharma Manufacturers Association (KPBMA). PhIRDA and KPBMA officially signed the MoU, which will further promote collaboration and exchange between the pharmaceutical industries of China and South Korea.

December 2

The Ministry of Civil Affairs released the *2024 National Social Organization Evaluation Levels (Second Batch) Announcement,* and PhIRDA has been awarded the 4A national social organization again.

December 3

2024 the First "Star of the Greater Bay Area" Biopharmaceutical Original Innovation Forum (BOIP), hosted by PhIRDA, was held in Shenzhen.

December 10

PhIRDA and the China Center for International Economic Exchanges co-organized the Symposium on Accelerating the Development of Commercial Medical Insurance.

December 12

PhIRDA submitted the Proposal on Improving the Policies Related to the Hong Kong Stock Connect to the China Securities Regulatory Commission.

December 13

Executive President Song Ruilin was invited to attend the 27th Biweekly Consultation Symposium hosted by National Committee of the Chinese People's Political Consultative Conference (CPPCC), and engaged in discussions on Accelerating the R&D and Clinical Application of Innovative Drugs and High-End Medical Devices.

Entrusted by the Department of International Economic Relations of the Ministry of Finance, PhIRDA organized members to attend the Symposium on Investment Cooperation with the UK.

December 18

Executive President Song Ruilin was invited to attend the Bioeconomy Special Research Seminar held by the Innovation-driven Development Center of the National Development and Reform Commission.

December 20

Entrusted by the Center for Drug Evaluation of NMPA, PhIRDA organized members to attend the Symposium on Encouraging and Promoting Innovation and Research & Development of Rare Disease Drugs.

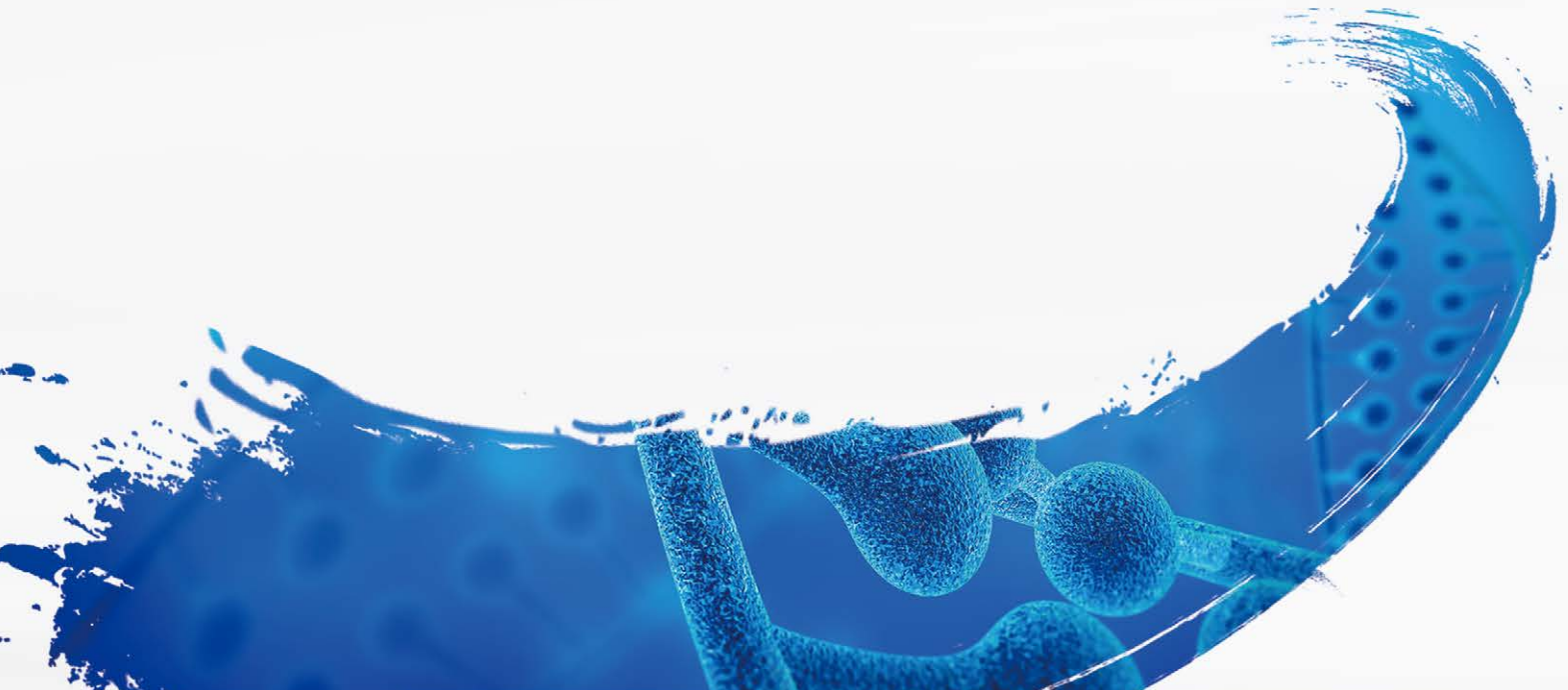
December 30

PhIRDA submitted the *Suggestions on Further Developing Commercial Health Insurance* to the Department of Comprehensive System Reform, National Development and Reform Commission.

Nanjing Legend Biotech, Wuhan Createrna Science and Technology and Lansheng Supply Chain Management (Shanghai) joined PhIRDA.

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创新型企业、科研机构、临床研究机构、投资机构等医药行业相关机构和个人自愿结成的全国性、行业性社会团体。

本会简称中国药促会，英文名称为 China Pharmaceutical Innovation and Research Development Association，缩写为 PhIRDA。

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，坚持以马克思列宁主义、毛泽东思想、邓小平理论、“三个代表”重要思想、科学发展观、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，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，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。

本会党的工作接受中央社会工作部的统一领导。本会接受民政部、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。

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，深入研究中国医药体系创新的相关问题，及时提出中国医药创新发展的政策建议；

（二）组织和开展有关医药行业发展的学术交流活动，围绕药械科研、技术协作及科技成果的推广，促进医药高科技的产业化、专业化；

（三）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；

（四）聚焦医药行业重点问题，搜集、整理、研究、传递医药科技研发信息，并开展咨询服务；

（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、法规等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和个人会员。

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）在本会的业务范围内具有一定的影响；

（三）本会要求的其他条件。

本会不强制或者变相强制公民、法人或者其他组织加入本会。

第九条 会员入会的程序是：

（一）提交入会申请书；

（二）提交有关证明材料；

（三）由理事会或理事会授权的机构讨论通过；

（四）由本会理事会或其授权的机构颁发会员证，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）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。

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。

第十四条 会员有下列情形之一的，由理事会或理事会授权的机构确认后丧失会员资格：

（一）2 年不按规定交纳会费；

（二）2 年不按要求参加本会活动；

（三）不再符合会员条件；

（四）丧失民事行为能力。

第十五条 会员因退会、被除名或者第十四条有关情形被确认丧失会员资格的，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、理事、监事名册，对会员、理事、监事情况进行记载。会员、理事、监事情况发生变动的，应当及时修改会员、理事、监事名册，并向会员公告。本会负责妥善保存会员、理事、监事相关档案，以及会员大会、理事会决议等原始记录。

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等重大事项；

（三）制定和修改理事、负责人、监事产生办法，其中负责人产生办法报中央社会工作部备案；

（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。

换届的会员大会应当采用现场会议方式；其他会员大会可采用现场会议、视频会议、现场和视频会议相结合、通讯会议等方式。

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 1/5 以上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，决定本会名称变更、终止，须经到会会员 2/3 以上投票表决通过；

（二）选举理事，当选理事得票数不得低于到会会员的 1/2；

罢免理事，须经到会会员 1/2 以上投票通过；

（三）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；

（四）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 70 人，且一般不得超过会员的 1/3。

理事不能来自同一会员单位，不在本会领取薪酬，

但与本会签订劳动合同的除外。

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）在本会业务范围内具有较高影响力。

第二十二条 理事的选举和罢免：

（一）第一届理事由发起人与申请成立时的会员共同会商提名，按程序经会员大会选举产生；

（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），负责换届选举工作；

换届工作领导小组（或专门选举委员会）拟订换届方案，应在会员大会召开前 2 个月报中央社会工作部审核；换届或届中调整工作中酝酿提名负责人人选，应当充分听取行业管理部门等方面意见，主动与中央社会工作部沟通；负责人人选经中央社会工作部审核同意后，方可召开会议选举；

按照本章程规定，召开会员大会，选举和罢免理事；

（三）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履行理事职责。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）谨慎、认真、勤勉、独立行使被合法赋予的职权；

（四）接受监事对其履行职责的合法监督和合理建议；

（五）不利用理事职权谋取不正当利益；

（六）不从事损害本会合法利益的活动；

（七）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。

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，审议法定代表人变更事项；

（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）决定会员的吸收和除名；

（七）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；

（八）决定副秘书长、各所属机构主要负责人；

（九）领导本会各所属机构开展工作；

（十）审议年度工作报告和工作计划；

（十一）审议年度财务预算、决算；

（十二）制定财务管理制度、信息公开办法、分支机构管理办法等重要的管理制度；

（十三）决定本会负责人和工作人员的考核及薪酬管理办法；

（十四）审议活动资金变更事项；

（十五）审议住所变更事项；

（十六）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，须由理事会全体理事 2/3 以上表决通过。提前或者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 2 次不出席理事会会议，自动丧失理事资格。

第二十九条 负责人由理事会采取无记名投票方式从理事中选举产生。

罢免负责人，须经到会理事 2/3 以上投票通过。

第三十条 选举负责人，按得票数确定当选人员，

但当选的得票数不得低于总票数的 2/3。

第三十一条 理事会每年至少召开 1 次会议，情况特殊的，可采用通讯形式召开。除视频会议外，其他通讯形式会议不得决定负责人的调整。

第三十二条 经会长或者 1/5 以上的理事提议，应当召开临时理事会会议。

会长不能主持临时理事会会议的，由提议召集人推举本会一名负责人主持会议。

第三节 负责人

第三十三条 本会负责人包括会长 1 名，副会长不超过 20 名，秘书长 1 名。

本会负责人应当具备下列条件：

（一）坚持中国共产党领导，拥护中国特色社会主义，坚决执行党的路线、方针、政策，具备良好的政治素质；

（二）遵纪守法，勤勉尽职，个人社会信用记录良好；

（三）具备相应的专业知识、经验和能力，熟悉行业情况，在本会业务领域有较大影响；

（四）身体健康，能正常履责，最高任职年龄不超过 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）未被确认为失信被执行人；

（八）无法律、法规、国家有关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。会长和秘书长不得为来自同一单位的在职人员，但与本会签订劳动合同的除外。负责人之间不得存在近亲属关系，且不得为来自同一会员单位的在职人员。

第三十四条 本会负责人任期与理事会相同，连任不超过 2 届。因特殊情况需要延长任期的，须经理事会表决通过，报中央社会工作部审核同意并报登记管理机关备案。

聘任的秘书长连任届次不受限制。

第三十五条 会长为本会法定代表人。

因特殊情况，经会长推荐、理事会同意，报中央社会工作部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。聘任的秘书长不得担任本会法定代表人。

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。

第三十六条 担任法定代表人的负责人被罢免或卸任的，本会应当在按程序决定新的法定代表人后 20 日内，向中央社会工作部报告，并向登记管理机关申请办理变更登记。

原任法定代表人不予配合办理法定代表人变更登记的，本会可根据有效的理事会同意变更的决议，由新的法定代表人签字，向登记管理机关申请变更登记。

第三十七条 会长履行下列职责：

（一）召集和主持会员大会、理事会；

（二）检查会员大会、理事会决议的落实情况；

（三）向会员大会、理事会报告工作。

会长、法定代表人应每年向理事会述职。

会长不能履行职责时，由其委托或理事会推选 1 名副会长代为履行职责。

第三十八条 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）处理其他日常事务。

第三十九条 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，理事会决议同时由出席会议成员确认。会议纪要、会议决议应当以适当方式向会员通报，备会员查询，并至少保存 30 年。

拟免职负责人的，应当在免职决议作出前 20 日向中央社会工作部报告；新选任负责人的，应当在选任决议作出后 20 日内向中央社会工作部报告。负责人发生

变动的，应当在变动决议作出后 30 日内报登记管理机关备案。

理事、负责人的变动情况应当及时向会员通报、备会员查询，并向社会公开。

第四节 监事

第四十条 本会设监事 1-6 名。监事任期与理事任期相同，期满可以连任。

本会接受并支持委派监事的监督指导。

第四十一条 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。

第四十二条 本会的负责人、理事和财务管理人员不得兼任监事。

第四十三条 监事行使下列职权：

（一）列席理事会，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的工作和提出提案；

（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）向中央社会工作部、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。

第四十四条 监事应当遵守有关法律、法规和本章程，忠实、勤勉履行职责。

第四十五条 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。

第五节 分支机构、代表机构

第四十六条 本会可以按照国家有关规定在本会的宗旨和业务范围内，按照确有工作需要且与本会管理能力相适应的原则设立分支机构、代表机构。本会的分支机构依据会员组成特点、业务范围的划分等设立，代表机构依据本会授权在规定地域内代表本会开展联络、交流、调研活动。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，按照本章程规定的宗旨和业务范围，在本会授权的范围内开展活动，法律责任由本会承担。

本会将分支机构、代表机构设立、变更、终止等信息及时向社会公开。

第四十七条 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。

第四十八条 本会依法设立的分支机构名称应当以“分会”、“专业委员会”、“工作委员会”、“专家委员会”、“技术委员会”等准确体现其性质和业务领域的字样结束；代表机构名称应当以“代表处”、“办事处”、“联络处”字样结束。分支机构、代表机构名称，除冠以本会名称外，不得以法人组织名称命名；在名称中使用“中国”、“全国”、“中华”等字词的，仅限于行（事）业领域限定语。

本会内部设立的办事机构名称，应当以“部”、“处”、“室”等字样结束，除冠以本会名称外，不得以法人组织名称命名，且区别于分支机构、代表机构名称。

第四十九条 分支机构、代表机构负责人的最高任职年龄不得超过 70 周岁，连任不超过 2 届。

第五十条 分支机构、代表机构的财务应当纳入本会法定账户统一管理，全部收支应当纳入本会财务统一核算。

第五十一条 本会在年度工作报告中将分支机构、代表机构的有关情况报送登记管理机关。同时，将有关信息及时向社会公开，自觉接受社会监督。

第六节 内部管理制度和矛盾解决机制

第五十二条 本会建立各项内部管理制度，完善相

关管理规程。建立《会员管理办法》《会费管理办法》《理事会选举规程》《会员大会选举规程》《信息公开办法》《财务管理制度》《资产管理制度》《内部控制制度》《分支机构管理办法》等相关制度和文件。

第五十三条 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住所，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，应当与接管人员办清交接手续。

第五十四条 本会证书、印章遗失时，经理事会2/3以上理事表决通过，在公开发行的报刊上刊登遗失声明，按规定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。

第五十五条 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

第五十六条 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。

第五十七条 本会按照国家有关规定收取会员会费。

第五十八条 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。

第五十九条 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。

第六十条 本会配备具有专业能力的会计人员。会计不得兼任出纳。会计人员应当进行会计核算，实行会计监督。会计人员调动工作或者离职时，应当与接管人员办清交接手续。

第六十一条 本会的资产管理执行国家规定的资产、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，应当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。

第六十二条 本会重大资产配置、处置须经过会员大会或者理事会审议。

第六十三条 理事会决议违反法律、法规或本章程规定，致使本会遭受损失的，参与审议的理事应当承担责任。但经证明在表决时反对并记载于会议记录的，该理事可免除责任。

第六十四条 本会换届或者更换法定代表人之前应当进行财务审计。

法定代表人在任期间，本会发生违反《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，导致本会发生违法行为或造成财产损失的，法定代表人应当承担个人责任。

第六十五条 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

第六十六条 本会依据有关法规政策，履行信息公开义务，建立信息公开制度，及时向会员公开负责人名单、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、承接政府转移或委托事项、可提供服务事项及运行情况等信息。

第六十七条 本会建立新闻发言人制度，经理事会通过，任命或指定1-2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。

第六十八条 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。

第六十九条 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。

第七十一条 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，在 30 日内报登记管理机关核准，并自登记管理机关核准后 30 日内向社会公开。

第八章 终止程序及终止后的财产处理

第七十二条 本会终止动议由理事会提出，报会员大会表决通过。

第七十三条 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。

第七十四条 本会清算后的剩余财产，在登记管理机关和相关部门的监督下，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。

第七十五条 本会经登记管理机关办理注销登记手续后即为终止。

第九章 附则

第七十六条 本章程经 2025 年 6 月 18 日第 19 次会员大会表决通过。

第七十七条 本章程的解释权属于本会的理事会。

第七十八条 本章程自登记管理机关核准之日起生效。

BRIEF INTRODUCTION TO PhIRDA

Chapter I: General Principle

Article 1. China Pharmaceutical Innovation and Research Development Association (PhIRDA) is a nationwide industrial organization, which consists of enterprises excelling at innovation, research institutions, clinical institutions, investment institutions, and organizations and individuals in the pharmaceutical industry.

Its English name is "China Pharmaceutical Innovation and Research Development Association", abbreviated as "PhIRDA".

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 Marxism-Leninism, Mao Zedong Thought, Deng Xiaoping Theory, the Theory of Three Represents, the Scientific Outlook on Development and Xi Jinping Thought on Socialism with Chinese Characteristics for 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, enhance the international competitiveness of China's pharmaceutical industry, protect the legitimate rights and interests of members, 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 unified 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.

PhIRDA's Party work is under the unified leadership of Society Work Department of the CPC Central Committee.

PhIRDA receives administration by the Ministry of Civil Affairs of the People's Republic of China, and the 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.

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 Chinese pharmaceutical innovation system, timely propose the suggestions for development of Chinese pharmaceutical industry.

(2) To organize and conduct events and academic exchanges for the development of the pharmaceutical industry, promote the combination of scientific research and practices in pharmaceutical and medical devices industry, advance the relevant research cooperation and academic-achieve transformation, and assist to industrialization and specification of the high technology.

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

(4) To focus on key issues in the pharmaceutical industry, collect, organize, research and spread information on pharmaceutical R&D, and provide consulting services.

(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 shall be carried out upon approval according to law.

Chapter III: Members

Article 7. PhIRDA Members: Institutional and individual

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.
PhIRDA shall not compel or indirectly compel citizens, legal entities, or other organizations to join the association.

Article 9. Procedures of joining the Association:
(1) Submit application;
(2) Submit other relevant materials;
(3) Being approved through discussion by the Board of Directors or an institution authorized by the Board of Directors;
(4) Membership will be issued by the Association or its authorized institution, with public announcement.

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 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.

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:
(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.

Article 14. The member shall lose their membership upon confirmation by the Board of Directors or an institution authorized by the Board of Directors under any of the following circumstances:
(1) Refuse to pay membership dues on time as per the stipulation for 2 year;
(2) Refuse to participate the activities of the Association as per the stipulation for 2 year;
(3) No longer meet the membership conditions;
(4) Loss of the capacity of civil conduct.

Article 15. A member's corresponding duties, rights, and obligations within the Association shall automatically terminate upon the resignation, expulsion, or confirmation of loss of membership due to the circumstances outlined in Article 14.

Article 16. A roster of members, directors, and supervisors, make a record on relevant information about them. In the event of any changes to the status of members, directors, or supervisors, the roster shall be updated accordingly and an announcement made to the members. The records of members, directors, and supervisors, as well as the original records of the PhIRDA General Assembly and Board of Directors' resolutions, shall be properly preserved.

Chapter IV: Organization Structure

Section One: PhIRDA General Assembly

Article 17. The PhIRDA General Assembly is the powerful organization of the Association. Function of the PhIRDA General Assembly includes:
(1) Composing and revising the Constitution of the Association;
(2) Deciding on major matters including the objectives and development plan of the Association;
(3) Formulating and revising the method of electing Directors, persons in charge, and Supervisors with the method for selecting persons in charge to be filed with Society Work Department of the CPC Central Committee;
(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 once every five years.
The Association shall notify its members of the PhIRDA General Assembly at least 15 days in advance.
The PhIRDA General Assembly involving the election of members shall be held in person; Other General Assembly may be held in person, via video conference, through a combination of in-person and video conference, or via teleconference.

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 over 1/5 of the members shall preside over the meeting.

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) The adoption and amendment of the Constitution, as well as decisions on changes to the association' s name or termination, must be approved by a vote of 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; The recall of a Director shall be approved by more than 1/2 of the members present;
(3) 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;
(4) 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 70, and in general, shall not exceed 1/3 of the total membership.
Directors shall not come from the same member and shall not receive remuneration from the Association, except for those who have signed labor contracts with the Association.
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 relatively significant influences in the business activities 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 then elected by the PhIRDA General Assembly in accordance with procedures;
(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 to be responsible for the election of the new term;
The leading group (or special election committee) shall draft a term change plan, which shall be reported to the Society Work Department of the CPC Central Committee for review and approval 2 months prior to the convening of the PhIRDA General Assembly; During the term change or mid-term adjustment, for the nominations for person in charge, the leading group should fully consider opinions from industry administrative departments and other relevant parties, and proactively communicate with the Society Work Department of the CPC Central Committee. With the consent of the Society Work Department of the CPC Central Committee, nominations for persons in charge could only be presented for election;
In accordance with the provisions of Constitution, the PhIRDA General Assembly shall be convened to elect and remove directors.
(3) 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 fulfill the responsibilities of 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) To exercise the functions and powers lawfully conferred with prudently, seriously, diligently and independently;
(4) To accept the lawful supervision and reasonable suggestions of Supervisors on their performance of duties;
(5) Not to use the authority of Directors for illegitimate interests;
(6)Not to engage in activities damaging the legitimate interests of the Association;
(7) .Not to disclose confidential information related to the Association obtained during the term, except as otherwise provided by laws and regulations.

Article 26. Functions of the Board of Directors:
(1) Implementing the decisions by PhIRDA General Assembly;
(2) Electing and recalling the persons in charge and deliberating on matters related to the change of the legal representative;
(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 admission and removal of members;
(7) Making decision on the establishment, modification and termination of branches, representative offices, offices and other subordinate bodies;
(8) Nominating the deputy secretary-general and the principal responsible persons of all subordinate institutions;
(9) Leading the work of the institutions affiliated to the Association;
(10) Deliberating on annual work reports and work plans;
(11) Deliberating on annual financial budget and final settlement;
(12) Formulating the financial management system, information disclosure procedures, and management regulations for branches and other important management systems;
(13) Deciding on the measures for the assessment and salary management of the person in charge and staff of the Association;
(14) Deliberating on matters related to changes in activity funding;
(15) Deliberating on matters related to changes in the registered address;
(16) 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 a vote of more than 2/3 of the Board of Directors. The term change shall not be advanced or 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 be held at least once a year, and may convene in the form of online or telephone communication if the circumstances are special. However, except for video conferencing, meetings conducted through other communication methods shall not be used to make decisions regarding the adjustment of the person in charge.

Article 32. An interim Board of Directors meeting shall be convened upon the proposal of the Chairman or at least 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: Association Leaders

Article 33. The leaders of the Association include one Chairman, not more than twenty Vice Presidents and one Secretary-General.
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) Possessing 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) Not identified as a person subject to enforced execution;
(8) 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 organization, except where a labor contract is signed with the Association. There shall be no close family relationships between the persons in charge, and they shall not be employed by the same member.

Article 34. 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. If it is necessary to extend the term of office due to special circumstances, it must be approved by a vote of the Board of Directors, submitted to the Society Work Department of the CPC Central Committee for review and approval, and filed with the registration authority.
The appointed Secretary-General may be reappointed without any restriction on the number of terms.

Article 35. The Chairman is the legal person of the Association.
Under special circumstances, upon the nomination of the Chairman and the Board of Directors, and upon the review and approval of the Society Work Department of the CPC Central Committee and the approval of the registration authority, the Vice President or the Secretary-General may act as the legal person. The Secretary-General employed 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 36. After the person in charge who serves as the legal person is recalled or leaves office, the Association shall, within 20 days of deciding on a new legal representative in accordance with the procedures, report to the Society Work Department of the CPC Central Committee and apply to the registration authority for change.
Where the former legal person fails to cooperate in the modification registration of the legal person, the Association may, according to the valid resolution of the Board of Directors on approving the modification, report to the administrative department for review and approval, have the new legal representative sign and then apply to the registration authority for registration modification.
Article 37. Function and powers executed by the Chairman:
(1) Calling for and hosting the PhIRDA General Assembly and meetings of the Board of Directors;
(2) Examining the implementation of decisions made by the PhIRDA General Assembly and meetings of the Board of Directors;
(3) Report work to the PhIRDA General Assembly and the Board of Directors.
The Chairman and legal person 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 38. 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) In charge of executing other routine affairs.

Article 39. Meeting summary shall be made for the PhIRDA General Assembly and meetings of Board of Directors. Where a decision is made, a written report shall be made and confirmed by the members present at the meeting. The meeting summary and decisions of the meeting shall be circulated to the members in an appropriate manner, made available for their reference, and preserved for at least 30 years.
If the removal of a person in charge is proposed, the Society Work Department of the CPC Central Committee shall be notified 20 days prior to the adoption of the removal resolution. If a new person in charge is appointed, the Society Work Department of the CPC Central Committee shall be notified within 20 days after the resolution of appointment is made. Any change in the person in charge shall be reported to the registration authority for filing within 30 days after the resolution regarding the change is made.
Changes in the members of the Board of Directors and persons in charge shall be promptly circulated to the members, made available for their reference, and publicly disclosed.

Section Four: Supervisors

Article 40. 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 41. 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 42. The leaders of the Association, the Directors and the financial management personnel shall not concurrently serve as Supervisors.

Article 43. The functions executed by the Supervisors include:
(1) To attend the Board of Directors 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 Society Work Department of the CPC Central Committee, industry administrative department, registration authority and competent taxation and accounting departments;
(6) To decide on other matters to be deliberated by the Supervisors.

Article 44. The Supervisors shall abide by the relevant laws and regulations and the Constitution, and perform their duties fully and faithfully.

Article 45. 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 Five: Branch and representative office

Article 46. The Association shall, in accordance with relevant national regulations and within the scope of its objectives and business, establish branches and representative offices within the business range and purpose of the Association and in accordance with the principle of being consistent with

the Association's management capacity. The branches of the Association shall be established based on the composition of members and the division of business scope, while the representative offices shall be authorized by the Association to conduct liaison, communication, and research activities within the designated regions. 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 under the scope authorized by the Association, in accordance with the objectives and business scope specified in this Constitution. The legal liabilities shall be assumed by the Association.

The Association shall promptly disclose to the public regarding the establishment, modification, or termination of its branches and representative offices.

Article 47. The Association will not establish regional branches or reestablish sub-branches or sub-representative offices.

Article 48. The names of the branches of the Association shall be ended with the words such as 'branch', 'specialty committee', 'working committee', 'expert committee,' or 'technical committee,' accurately reflecting their nature and business scope. The names of representative offices shall be ended with words such as 'representative office,' 'office,' or 'liaison office'. The names of branches and representative offices, in addition to bearing the Association's name, shall not be named after any legal entity. The use of terms such as 'China,' 'National,' or 'Chinese' in the name shall be limited to descriptive terms related to the specific business or industry sectors.

The names of the administrative offices established within the Association shall be ended with the terms such as 'Department,' 'Division,' or 'Office.' In addition to bearing the Association's name, the offices shall not be named after any legal entity and must be distinguishable from the names of branches or representative offices.

Article 49. 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 50. The financial affairs of branches and representative offices shall be subject to the unified management of the statutory accounts of the Association, and all revenues and expenditures shall be included in the Association's consolidated financial accounting.

Article 51. 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 Six: Internal management system and conflict resolution mechanism

Article 52. The Association shall establish various internal management systems and improve relevant management procedures. The Association shall formulate *Measures for Member Management, Measures for Membership Fee Management, Rules for the Election for the Board of Directors, Rules for the Election of Members of the PhIRDA General Assembly, Measures for Information Disclosure, Regulations for Financial Management, Regulations for Asset Management, Regulations for Internal Controls, Measures for the Branch Management* and other relevant regulations and documents.

Article 53. 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 should go through handing-over procedures with the managing staff and shifting persons.

Article 54. 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 for re-development or engraving shall be made according to regulations. If they are illegally embezzled by an individual, it shall be required to return through legal means.

Article 55. 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 56. 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 57. The Association shall collect membership fees in accordance with the relevant regulations of the State.

Article 58. The income of the Association shall be used for the business range stipulated in this Constitution, except for the reasonable expenses related to the Association.

Article 59. 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 60. The Association employs professional and qualified accounting staff. The accountant cannot additionally serve as the cashier. Accountants should perform accounting and accounting supervision. If accountants leave or are transferred, they should go through handing-over procedures with the managing staff and shifting persons.

Article 61. Management of assets of the Association shall be executed according to the assets and 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 62. The allocation and disposal of major assets of the Association shall be deliberated by the PhIRDA General Assembly or the Board of Directors.

Article 63. Where a resolution of the Board of Directors violates any law, regulation or articles of association, thereby causing losses to the Association, 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 64. Prior to any replacement or the expiration of the legal person of the Association, he/she should 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 the Association is caused due to the legal person’s dereliction of duty, the legal person shall bear individual liabilities.

Article 65. 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 66. In accordance with the relevant regulations and policies, the Association shall perform the obligation of information disclosure, establish an information disclosure system, timely provide members with the list of persons in charge, 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.

Article 67. The Association shall establish a spokesperson system. 1 or 2 spokespersons, 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 68. The Association shall establish an annual report system, which shall be timely disclosed to the public and

subject to public supervision.

Article 69. 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 70. 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 71. The Constitution of Association amended by the Association shall be submitted to the registration authority for review and approval after being adopted by more than 2/3 of the members being presented in the PhIRDA General Assembly . After approval, the amended Constitution shall be made publicly available within 30 days.

Chapter VIII: Termination Procedure and Post-dissolution Assets management

Article 72. The termination of the Association shall be proposed by the Board of Directors and be submitted to the PhIRDA General Assembly for vote.

Article 73. 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 74. The registration shall be terminated after the registration authority has gone through the formalities for cancellation of registration. The remaining property after the liquidation 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 and registration authority in accordance with the relevant provisions of the State.

Article 75. The registration shall be terminated after the registration authority has gone through the formalities for cancellation of registration.

Chapter IX: Appendix

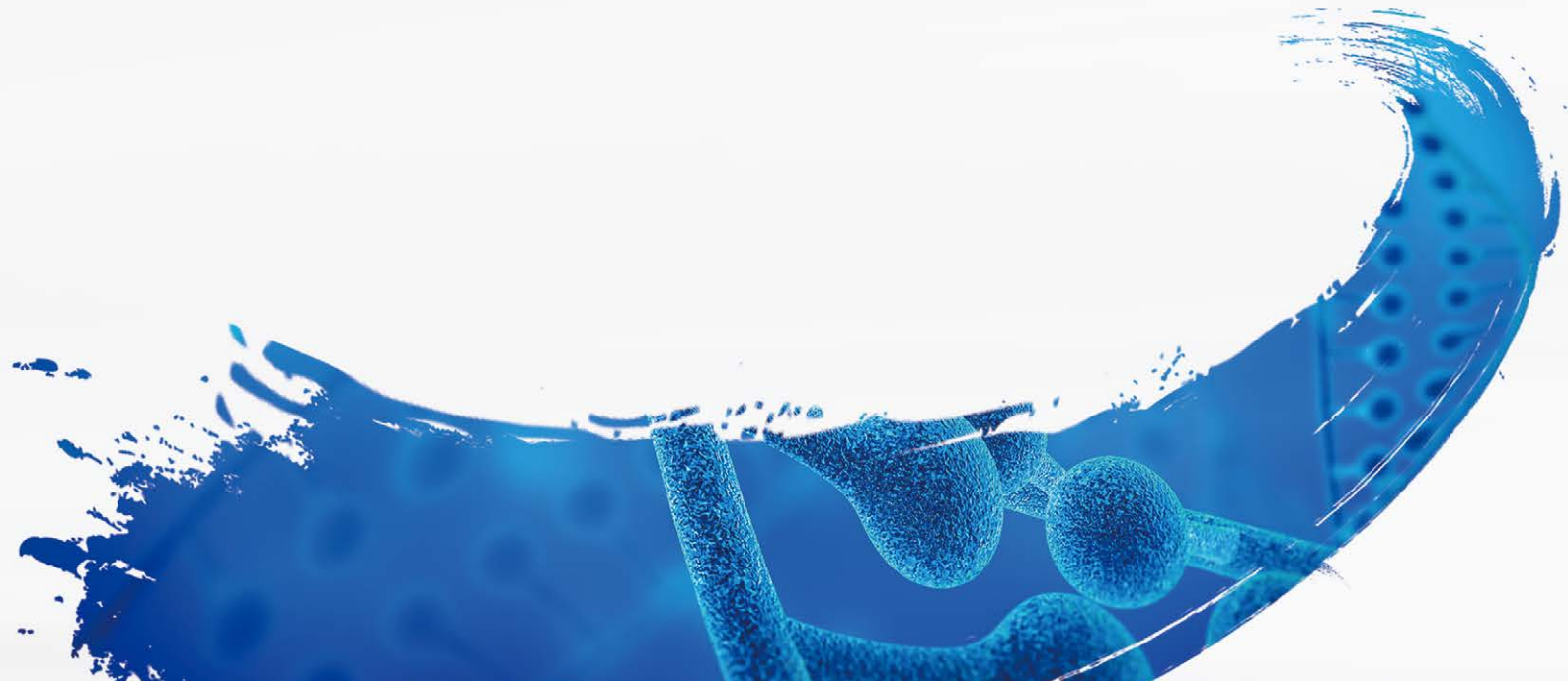
Article 76. This Constitution was approved by the 19th PhIRDA General Assembly on day, June 18th, 2025.

Article 77. The right of interpreting this Constitution belongs to PhIRDA Board of Directors.

Article 78. The Constitution comes into force on the date when it is approved by the authority of registration & administration.

2024 年度工作报告暨 2025 年度工作建议

2024 Annual Work Report & 2025 Work Proposal



2024 年度工作报告暨 2025 年度工作建议

2024 年，生物医药行业在机遇与挑战的交织中砥砺奋进。中国药促会坚守使命，积极履行职责，在促进政策完善方面，深入研究药械产业环境和面临的痛点问题，及时提出政策建议，协助会员单位解决实际问题；在加强国际交流合作方面，与国内外医药行业协会、企业、科研机构等广泛合作，为会员单位搭建国际交流平台，推动国际医药产业的多方位合作；在推动行业创新发展方面，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，营造更有吸引力的医药创新投资环境，在多个方面均取得了显著成绩，为我国生物医药行业的发展做出了积极而卓越的贡献。我会 2024 年度工作完成情况及 2025 年工作建议如下：

第一部分 2024 年度工作回顾

一、筑牢思想根基，以党建为魂引领协会破浪前行

我会党支部始终坚持以习近平新时代中国特色社会主义思想为指导，深入贯彻党的二十大和二十届二中、三中全会精神，扎实推进党支部标准化、规范化建设，不断提高党建工作质量，以党建引领协会高质量发展。聚焦政治建设，坚持“第一议题”制度，及时跟进学习贯彻习近平总书记重要讲话和重要指示批示精神；根据全国性行业协会商会党委和中国工业经济联合会党委统一部署要求，扎实开展党纪学习教育，进一步增强支部党员的纪律意识，教育引导党员干部学纪、知纪、明纪、守纪；加强组织建设，在严格落实“三会一课”同时，精心策划组织开展形式丰富的主题党日活动，在多样性的实践与学习中，提升全体党员党性修养；按照发展党员工作的有关规定，报告期内，我会党支部 2 名预备党员期满转正，并确定 2 名积极分子。

二、充分发挥高端智库优势，向中央多个部委提交建议举措，促进全链条支持医药创新政策

（一）秉持新发展理念，聚焦创新发展的矛盾与问题，向国家相关部委提交建议报告，推动产业高质量发展

在当前生物医药创新发展战略和新质生产力理念的大背景下，向中国农工民主党中央委员会提交《关于开展创新药发展有关支持政策调研考察建议报告》，以推动强化政策统筹促进医产研学用的深度融合，加快培育具有竞争力的创新体系和生态环境，激发原始创新活力和动力；受国家发展和改革委员会体制改革综合司委托开展新质生产力专题研究，多次开展研讨和调研，形成《关于打通生物医药创新全链条堵点卡点 促进新质生产力发展的研究报告》，以促进建立符合创新发展的新型政医产学研用资关系。

在国家颁布《浦东新区综合改革试点实施方案（2023 — 2027 年）》，明确支持浦东新区打造社会主义现代化建设引领区的背景下，向上海市浦东新区人民政府提交《关于推动“浦东方案”落地的建议举措》，对“允许生物医药新产品参照国际同类药品定价”相关举措提出建议，以推动与国际接轨的定价体系的相关政策尽快落地。

同时，应邀出席全国政协十四届常委会第七次会议与十四届全国政协第二十七次双周协商座谈会，积极为医药产业创新发展建言献策。

（二）高度关注政策制定与执行协同产业创新发展，推动各部门政策取向一致性，解决行业急难愁盼

一是高度关注药品价格政策影响，积极反映行业痛点与诉求。拜访国家医保局价采司、参加新上市化学药品首发价格形成指引座谈会，表达行业关切与诉求，提倡坚持自主定价权，维护创新主体权益；并通过第十一届理事会第 18 次会议商讨，形成《关于建立新上市化学药品首发价格形成机制鼓励高质量创新的通知（征求意见稿）》的相关建议，反馈至国家医保局。

二是完善药物国家政策，推进“三医”协同治理与医药创新发展。受国家卫生健康委员会药物政策与基本药物制度司委托，开展国家药物政策专题研究工作，形成《围绕提升新药临床价值、推进全链条药物政策系统性建设》专题研究报告，以推动国家卫生健康、发展、改革、科技、工信、药品监管、医保等多个部门的协调联动，助力产业、科技、金融、医保、医疗、医药政策取向一致形成政策合力，为完善国家药物政策体系提供参考。

三是深化体制机制改革，持续推进我国药械监管能力建设与制度改革。召开会员企业交流座谈会，梳理产业面临的注册、生产等有关问题，向国家发展改革委价格成本调查中心提交《关于深化药品注册审评工作，促进药品创新和行业发展的建议》，以优化审评资源配置提高服务效能；向国家药监局提交《关于持续深化药品监管改革有关问题的建议报告》《关于中国创新医疗器械审评制度改革》等研究成果报告。

四是广泛向政府有关部门反映行业诉求，提高对医药创新产业发展的关注度。协助财政部国际经济关系司开展“关于创新药产业发展”、协助国家发展改革委价格成本和认证中心开展“药品注册收费情况”的调研座谈，参与国家发展改革委创新中心生物经济专题研究与研讨，向商务部外贸司提交《关于我国医药创新产业及贸易相关问题和建议的报告》等。

（三）持续关注罕见病患者用药保障问题

紧密跟随国家相关政策制度，深入了解产业发展及诊疗等不同阶段面临的难点与挑战，为构建罕见病法律体系、推动罕见病药物研发及优化患者诊疗等提供多元化的视角和策略，在全链条上强化罕见病药物的供应与保障能力。

三、捕捉产业发展动向，高质量开展课题研究，助力医药创新的政策环境与市场环境的不断完善

（一）聚焦“产学研医”全产业链深度结合，承接政府委托课题，推动临床实践与科研创新的紧密结合，形成创新周期的良好闭环

受北京市卫生健康委委托，持续开展“北京市研究型病房示范单位建设动态评估”工作，以评估促建设，根据前期评估过程中遇到的问题以及最新研究对研究型病房评估指标体系进行调整，举办专家座谈会对指标体系作进一步修订和完善。客观评估各示范单位在研究型病房基本建设、临床研究和成果转化方面取得的建设成效，总结第二批研究型病房 3 年建设成效，动态整理第三批研究型病房建设的阶段性成果，形成总结评估报告及政策建议。同步开展面向三批共 30 家示范单位优秀典型案例征集工作，汇编研究型病房优秀案例集。

（二）围绕行业发展的痛点堵点问题，开展课题研究，以期持续完善产业创新与国际化的发展生态

一是在国家药品监督管理局、国家药品监督管理局医疗器械审评中心领导指导下，开展“中国创新器械审评制度改革研究”工作，聚焦医疗器械审评管理体制机制与制约产业创新发展的问题，深入开展研究，以期建立国家统一、高效、科学的审评监管体系，提高审评监管能力、促进监管现代化，推进我国创新器械产业的高质量发展，同时为《医疗器械管理法》立法以及审评制度改革提供建议参考。

二是开展“中国创新药出海技术路径研究”，助力我国创新药开拓“一带一路”国际市场。从战略层面建议加强国内跨部门协作，构建与海外监管机构的协同合作网络。同时，从产业发展角度出发，提出建立白名单机制、援外医疗中优先采用国内创新药、鼓励开展全球多中心临床试验（MRCT）、促进产业界国际交流合作等方面的建议，提升本土创新药的国际认可度与国际知名度。

三是开展“国际化背景下创新药定价机制研究”，分析国际主流市场对创新药定价规则与机制，从完善市场机制角度，提出建立以市场为主导的药品价格形成机制的相关建议，以减少政府不当干预，助力本土创新企业在立足本国的同时也能在国际舞台上崭露头角。

四是开展“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。以突破高值创新药支付困境，探索构建适用于中国医保支付价与病人支付价相结合的创新支付模式，提出“ABC 共同支付模式”，以促进高值创新药品的可及性和国际竞争力。

五是在北京市卫健委指导下，联合有关单位（北京药学会、北京市临床试验机构、中国外商投资企业协会药品研制和开发工作委员会（RDPAC））开展“临床试验效能提升研究”系列课题研究，形成并发布《北京市药物临床试验合同共识》，为北京乃至全国创新能力的提升贡献力量。

四、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

（一）深度参与完善法律法规体系构建与制度深化研究

一是高度重视医疗器械法治建设工作，深度参与《医疗器械管理法》的立法讨论与建议环节。《医疗器械管理法》作为重要的顶层设计文件，其出台应不仅是对现

有监督管理体系的确认，还应具备前瞻性和系统性。我会及时召开企业座谈会并开展相关研究工作，拜会国家药监局器审中心和国家药监局注册司，围绕创新产业发展面临的障碍与审评体制机制改革等议题面对面沟通与交流，并提交《医疗器械管理法（征求意见稿）》的相关建议，以进一步深化医疗器械审评审批制度改革，为建立健全统一规范、高效管理且权威的国家医疗器械监管制度提供法制化保障。

二是参与基础性制度法规研讨，健全监管制度体系。受邀参与国家药监局组织的《中药标准管理专门规定（征求意见稿）》相关研讨会，推进符合中医药特点的中药标准管理体系建设；提交对《关于进一步优化临床急需境外已上市药品审评审批有关事项的公告》的相关建议，进一步提速增效，满足医疗机构临床用药需求等。

（二）建立政企沟通平台，拓宽政企合作渠道

应 CDE 委托，协助开展 2024 年指导原则制定目录、顾客满意度调查，以及起草相关意见的征集与反馈等工作；积极组织和推荐会员企业深度参与《以患者为中心的罕见疾病药物研发试点（“关爱计划”）》、CAR-T 细胞治疗产品风险控制、艾滋病免疫重建不全治疗药物临床研发、多肽药物的临床药理、药物警戒等相关指导原则的制修订。

五、积极拓宽发声渠道，扩大影响力

一是聚焦针对行业关切问题组织开展企业及专家座谈交流会。如国家卫生健康委三医协同推进药品供应保障制度建设交流会、中国国际经济交流中心完善创新药定价机制座谈会、“完善我国医保目录谈判制度”座谈会、“完善药品监管政策”座谈会等。并基于药品数据保护制度具体法规的缺失以及天然药物单独注册路径缺失面临的后续医保准入挑战，深入了解企业实际问题，向国家药监局、国家医保局等行业主管部门提交建议报告。

二是梳理总结产业发展和研究成果，发表学术文章、出版研究报告，为政策制定与完善提供理论参考和实证依据。二项研究报告参与书籍出版，发布期刊文章四篇。在《精准医学创新研究与产业发展报告》系列图书中发表《转化医学的生态建设及投融资机遇（章节）》，获评“清华大学出版社 2024 年医学优秀图书”；《药品上市许可持有人制度下的监管能力建设与区域产业升级——长三角地区经验概述》收录于《药品监管前沿研究（2023）》等。

《中国药品监管四十年变迁与思考》刊登于《中国药房》杂志，《创新多元支付体系以促进高值创新药物准入与实施的研究》发表于《中国医疗保险》期刊，《对我国医疗器械审评审批制度改革的思考》《WHO 监管评估体系对我国药品监管国际化的思考》先后刊载于《中国食品药品监管》。

六、深入开展国际医药交流，推动全球医药产业相互交流与合作

（一）积极参与国际规则制定，组织专家参与国内外药品监管标准指导原则的制修订工作，切实推动 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 29 个工作组推荐了 60 名专家（包括 11 名组长，9 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 37%。

二是受国家药品监督管理局 ICH 工作办公室委托，我会针对 71 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推荐工作，报告期内，已有 130 位我会推荐的专家被纳入 39 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、分析方法验证 / 分析方法开发等主题，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。

四是我会组织二十多家会员单位先后多次配合 CDE 开展电子申报资料网络传输试运行测试，为推进药品注册申请电子申报工作的顺利开展及全面实施奠定了基础。

五是我会推荐的 IFPMA ICH 四位专家分别现场参加了 2024 年 6 月和 11 月初在日本福冈、加拿大蒙特利尔线下召开的 ICH 大会中 M11、Q6（R1）、Q2/Q14、E2D（R1）指导原则工作组的相关工作会议，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）搭建中韩医药产业与投资界合作交流平台，

推动亚洲医药创新产业发展，打造重要区域性医药产业合作平台，深化亚洲在全球医药创新领域的重要地位

我会会长张抒扬、执行会长宋瑞霖先后两次分别与韩国制药生物协会（以下称“KPBMA”）卢允宏会长、李铉禹副会长进行友好会见，围绕推动中韩医药创新产业合作进行深入交流。基于打造中韩医药产业合作平台的共同目标，我会与 KPBMA 正式签署了合作备忘录，双方将建立常态化合作交流机制，定期交流互访；开展中韩医药产业合作，扩大中韩投资合作，共同推动中韩两国政府监管机构间合作，开放双方市场，为医药产品进入两国市场提供便利；中韩两协会轮流主办中韩医药产业创新大会，共同推动亚洲医药产业创新生态系统的构建，拓展中日韩三边医药领域的深度合作。

（三）加强与欧洲监管机构及医药行业协会的合作交流，推动中欧以及全球生物医药产业创新发展，造福全球患者

我会执行会长宋瑞霖于 6 月 24 日在北京与荷兰卫生、福利和体育部医疗服务副大臣胡梓吟进行友好会见，双方就推动中荷药监及产业界合作达成了共识，携手共同推动中荷两国药监机构建立统一的药品监管标准，缩短审评审批周期，加强临床领域和药品短缺问题的交流合作，促进两国医药产品的互流互通众。

我会执行会长宋瑞霖于 9 月 11 日在北京与欧洲制药工业协会联合会（以下称“EFPIA”）主席、诺和诺德全球总裁兼首席执行官 Lars Fruergaard Jørgensen 进行友好会见，并签署了合作备忘录。此次会晤为双方在生物医药领域开展长期、稳定的合作奠定了坚实基础，双方将充分发挥资源和平台优势，重点围绕药品研发、监管、知识产权和数据保护等方面开展合作，实现资源共享、优势互补，加速中欧药品上市进程，推动中欧医药产业高质量发展。

欧洲的生物技术发展迅猛，是中国开展医药产业合作的优先伙伴，也是我会国际合作重点开展的区域。与荷兰卫生相关部门及 EFPIA 的深入合作，将为推动中欧以及全球生物医药产业创新发展，造福全球患者做出积极贡献。

（四）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、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、沙特阿拉伯、阿联酋、新加坡等国家驻华使领馆及相关机构，以及 IFPMA、APAC 等国际组织保持紧密联系，共同推动全球医药产业相互交流与合作。

我会还受邀参加第十二届亚洲监管大会、第四届亚洲医疗健康高峰论坛、“知行中国——中美青年菁英项目”、中瑞医药创新产业闭门交流会等国际会议及项目，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。

（五）为中国创新产品走向国际搭建赋能平台，助力中国创新成果惠及更多全球患者

受沙特阿拉伯（以下称“沙特”）相关政府部门邀请，我会组织中国创新药械企业代表团于 2024 年 11 月 9 日 -13 日在沙特首都利雅得开展公务交流活动，与沙特卫生、药监、投资、采购、临床研究机构及当地药械企业开展交流座谈及实地参访。帮助参团企业切实了解当地招商引资政策，为中国医药企业融资、落地中东提供便利，为中国创新产品走向国际搭建赋能平台，助力中国创新成果惠及更多全球患者。

（六）受邀在国际媒体 PharmaBoardroom 撰文，向世界展示中国药监改革及医药产业创新成果

我会执行会长宋瑞霖及多位会员单位创新医药企业负责人先后接受 PharmaBoardroom 专访并在《2024 中国医疗与生命科学回顾》正式刊载，展现了中国在全球生物创新医药领域中的重要地位，尤其在创新药研发、产业化和国际化合作方面取得的显著成就。

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

近年来，我会凭借在行业内的深厚积淀与卓越影响力，组织策划医药创新与投资大会等多个重点项目；并充分发挥我会分支机构的专业优势，整合不同领域的专家资源，举办了医药创新政策论坛等一系列专业性强、品牌化程度高的活动，为满足药械产业需求提供多元化的解决方案。

（一）医药创新与投资大会

2024 年 11 月 30 日—12 月 1 日，我会联合香港交易所等机构共同主办的第九届医药创新与投资大会在广州成功举办。大会首次落地广州，依托粤港澳大湾区政策及区位优势，以“医药产业与资本融合创新，激发我国医药创新主体源头技术创新活力，塑造高质量发展的医药创新生态环境”为主题，邀请药械产业全链条各参与方，聚焦全球经济和合作形式、商业保险政策、投资并购、授权商业化、新药研发监管国际化、临床研究合作、细胞与基因治疗等前沿技术领域和产业热点话题，满足不同参会者多元化需求。大会组织 9 场专业论坛，80 余个创新项目现场路演，吸引近 2000 名观众参与，为参会各方搭建了资源共享、信息互通、合作互利，成果互惠的交流合作平台，共计 500 多场商务合作洽谈需求得到满足，受到业界广泛好评。

（二）溶瘤病毒创新与合作大会

为进一步推动溶瘤病毒药物临床研发，促进溶瘤病毒领域全链条交流与合作，由我会与武汉东湖新技术开发区管理委员会指导的第二届溶瘤病毒创新与合作大会于 2024 年 10 月 26 日—27 日在湖北武汉举行。大会设早期研发—工艺及安评、CMC 研究、临床研究、商业化及国际合作、行业标准制定、基础及临床转化、罕见病等七大主题论坛，邀请国内外产业界、学术界、投资界嘉宾结合自身实践分享溶瘤病毒审批监管领域法规与政策解读、产业研发现状及科研成果，探讨如何应对国内外创新药环境的新机遇、新挑战。

（三）合肥生物医药创新与产业大会

2024 年 9 月 6 日—7 日，由我会与合肥综合性国家科学中心大健康研究院、安徽省生命健康产业推进组办公室等单位共同组织的第二届合肥生物医药创新与产业大会在合肥隆重举行。大会共组织十余场论坛、路演、邀请百余位科学家、企业家、临床研究者、专业投资人和近千名专业观众参与，聚焦生物医药前沿，围绕抗体药物、细胞治疗药物、基因治疗药物等创新药物研究、开发、产业化与监管的热点和难点问题，共同探讨技术生态，展望产业合作发展新未来。

（四）“湾区之星”生物医药源头创新大会

2024 年 12 月 3 日，我会主办的 2024 首届“湾区之星”生物医药源头创新大会在深圳召开。大会聚焦“激活源头创新第一公里”，邀请国家及政府有关部门领导、世界顶级科学家、全球临床研究领军人、投资和金融服务领域知名投资人、药械产业领袖齐聚一堂，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，为产业增长激发创新动能。

（五）糖尿病和代谢性疾病药物器械研发创新大会

2024 年 4 月 27 日—28 日，由我会糖尿病与代谢性疾病药物临床研究和药物研发专业委员会联合主办的第二届糖尿病和代谢性疾病药物器械研发创新大会在成都举办。第二届大会特设十大主题论坛，邀请糖尿病及代谢性疾病领域权威医生、政策专家、企业领袖出席，聚焦糖尿病及代谢性疾病领域的药械创新要点、难点，紧密围绕临床需求，深入探讨创新研发解决方案。

（六）医药创新政策论坛

2024 年 6 月 21 日，我会医药政策专业委员会主办的 2024 医药创新政策论坛在上海举办。会议围绕“‘浦东方案’落地举措探讨”和“创新支付体系”两大主题，与现场观众共同呈现了一场聚焦医药创新、专家合力、政策解读、研判行业未来的高质量盛会。

（七）药械产业数智生物技术创新大会

2024 年 10 月 12 日，我会医药数字化及创新疗法、创新医疗器械专业委员会联合主办的药械产业数智生物技术创新大会在苏州举办，深度聚焦药械产业创新政策、创新技术研发、现代信息技术应用等主题，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。

八、不断汇聚高端资源要素，推动分支机构高质量发展，充分发挥分支机构专家智库作用，为推动我国药械产业高质量和可持续发展贡献新的力量

自 2024 年 2 月 22 日第十一届第 18 次理事会闭幕以来，我会依托分支机构专家及委员资源优势，在药械研发、临床研究、政策研究、国际交流合作、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，受到社会各界广泛关注和好评。根据我会分支机构管理办法的相关规定，2024 年 8 月，我会对分支机构委员进行了整体增补。经过严格的委员推荐和遴选程序，本次共增补 105 位新委员，其中 18 位来自 IFPMA ICH

工作组成员。增补完毕后，我会 13 个分支机构共有委员 832 人，为分支机构开展后续工作补充了新鲜血液。

（一）与国家政府有关部门保持紧密联系，积极参与药械全产业链上下游相关法律法规制、修订工作，代表药械创新主体发声

一是我会医药政策、创新医疗器械、医药数字化及创新疗法、药物临床试验、医药企业合规等专业委员会积极参与相关政府部门多项法律法规和指导原则的制、修订工作，形成多项课题研究成果和政策建议报告。相关意见和建议得到采纳。

二是 2024 年 12 月，我会药物研发、医药创新投资专业委员会组织生物科技公司、投资机构和服务机构等香港资本市场各参与方代表围绕港股通相关制度进行了研讨与交流，形成《关于完善港股通相关政策的倡议》报送中国证券监督管理委员会。

（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

2024 年 8 月 31 日，我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研究基金会等机构发布《2023 年度中国抗肿瘤新药临床研究评述》，并召开抗肿瘤药物创新研发大会，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

自 2020 年以来，我会及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、贝达药业和圣和药业，开展上市后临床应用观察与再评价服务项目，为满足患者临床用药需求贡献绵薄之力。

（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

为了适应合规领域相关法律规定和国际准则的最新变化，我会医药企业合规专业委员会联合 RDPAC 共同开展《医药企业伦理准则》修订相关工作，推动不同产业主体合规标准协调一致并与国际接轨。

（五）构建标准化、高质量的生物样本活库，为转化医学提供重要保证

2024 年，我会抗肿瘤药物临床研究、创新研发服务和医药企业合规专业委员会联合开展生物样本活库建设管理规范及发布专家共识相关工作，邀请行业领域专家参与“生物样本活库建设管理规范专家共识”的编写、审改及发布等工作，以期为临床生物样本的质量管理体系建立与标准化提供借鉴和参考。

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，深化与各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，我会积极探索政府园区、科研机构、高校、产业、资本、服务业多方跨界合作、融合发展新模式，围绕如何帮助地方政府和产业园区引入药械产业创新资源，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。2024 年以来，我会与上海、广州、合肥、成都、苏州等地方政府保持密切联系，并签署战略合作协议，为帮助地方政府及相关产业园区构建创新人才荟萃、创新主体集聚、创新成果涌流、创新活力迸发、创新环境卓越的世界一流高科技园区和现代化生物医药制造业集群贡献智力支持。

十、坚持“以会员需求为导向”的服务理念，加大会员单位调研力度与频率，完善会员服务机制与体系，增强会员单位“获得感”与凝聚力

为汇聚多元创新力量，我会积极挖掘优秀创新主体，优化完善会员结构，打造医药创新生态圈。经理事会表决，2024 年共吸纳 15 家新会员，截至 2024 年底我会共有各类会员单位 181 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。

2024 年我会结合行业热点难点、公司战略发展等议题，由会领导带队联合行业专家深入 13 家会员单位进行参观调研，并先后在上海、杭州、烟台等地组织召开区域性会员交流活动，通过多渠道听取会员单位意见，实现与会员单位的有机互动，增强行业信息传递及各方合作可能，推动产业链纵深链接，促进会员单位发展形成合力。

同时，我会积极响应会员服务需求，持续发挥资源整合优势和平台窗口作用，积极互通互鉴、深化交流合作，持续提升会员服务质量，以品牌会议、意见征集、政企座谈等为一系列举措落实会员单位诉求与建议，助

力政医产学研用资互联互通；通过搭建会员动态专栏、优化沟通对话机制等，为会员单位提供品牌宣传、信息推广及合作资源对接等丰富多元的会员服务，以实际行动助力不同阶段会员单位的高质量发展。

十一、践行社会责任，持续推动援藏助藏工作

8 月 14 日—18 日，由援助西藏发展基金会主办的 2024 年“西藏人人健康”院士专家进藏义诊活动在拉萨市和日喀则市举行。我会组织会员单位向义诊活动捐助所需药品，得到会员单位的积极响应、踊跃参与。恒瑞医药、齐鲁制药、上海医药、绿叶制药、信立泰药业、亚宝药业等会员单位捐助义诊药品。

第二部分 2025 年度重点工作建议

一、以习近平新时代中国特色社会主义思想为指导，全面贯彻党的二十大精神，以高质量党建引领协会高质量发展

新的一年，我会将继续以习近平新时代中国特色社会主义思想作为协会工作的指导思想，作为研究问题、解决问题的“总钥匙”。加强思想政治建设，通过开展专题讲座、交流研讨、实地调研等活动，深刻领会习近平总书记重要讲话和指示批示精神实质，做到学思用贯通、知信行统一。加强组织建设，创新党建活动形式和内容，严格落实“三会一课”、组织生活会、主题党日等组织生活制度，持续提升党支部凝聚力、战斗力，让党支部成为协会工作的坚强战斗堡垒。同时加强作风纪律建设，加强党员教育管理，立足行业特点和协会实际，搭建产学研合作平台，开展助推行业发展的活动，为行业发展贡献智慧和力量，推动行业高质量发展的成果检验党建工作的成效，实现党建工作与协会业务发展的同频共振、相互促进。

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

当前，全球经济格局正在重塑，创新版图正在重构，我们将持续围绕重点领域开展系统性研究和活动，分析各阶段制约创新循环发展的堵点和机制障碍，提出具有针对性的建议，持续推进创新链产业链资金链人才链深度融合，促进创新产业政策与市场政策的不断优化与完善。

一是重点关注国家对全链条支持创新药发展实施方案的进展，聚焦重大核心发展领域，主攻薄弱环节，巩固生物医药产业在国民经济中的战略性地位。针对医药源头创新和临床研究能力建设，承接北京市等相关部门对临床研究带动医药产业创新发展的相关专题，推动产业全链条创新协同发展。

二是开展“大健康背景下商业健康保险发展机制研究”。通过深入剖析当前商业健康保险发展体制机制障碍，探索建立与基本医保制度相衔接、适应中国国情的多层次医疗保障体系，补足商业健康保险的短板，增强创新药物的可获得性和可负担性，为“健康中国”目标实现提供强有力的保障支撑。

三是设立“创新药品目录准入及支付体系研究”，为创新药支付开拓创新思路，实现社保和商保优势互补，重点探索优化医保支付管理政策，尤其是创新药目录药品管理、准入和支付机制开展研究，引导保险业深度融合多层次医疗保障体系建设，完善医疗保障制度与促进医药创新的平衡。

四是设立“中国创新药械市场准入机制研究”课题，旨在通过深入分析国家政策文件、市场准入规则、产业发展趋势、医保报销政策、药品与医疗服务定价等关键领域，识别药品、医疗器械产业在准入过程中的瓶颈和阻碍，提出平衡保障管理效能与满足临床应用的政策建议，为药品、医疗器械产业新质生产力的发展提供更完善、坚实的制度基础。

五是开展“创新药械出海中东的机遇与挑战研究”课题，旨在深入挖掘中东地区的市场潜力，对当前出海的案例现状进行对比研究，分析当前出海面临的挑战，提出中国药械企业开拓国际市场的策略建议；并促进监管部门与产业界的国际合作，加速产业升级，不断增强国际竞争力。

六是关注前沿热点领域，开展“人工智能 +”药物研发领域课题，通过深入了解人工智能技术在新药创制的应用场景，分析该领域应用现状与监管难点，以在复合型人才的培养与引进、监管法规的建立、数据信息的保护、审评指导原则的制定等方面予以相关的具体建议，推动人工智能技术在医药领域的广泛应用，进而提升产业的创新能力和竞争力。

三、持续关注市场主体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》立法

进程，持续关注《价格法（修改）》《保险法（修改）》《社会保险法（修改）》等重大法律修订趋势，及时召开专题座谈会倾听产业建议，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，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。

四、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“一带一路”沿线国家医药产业合作交流

一是我会计划组织医药企业高级别代表团出访东盟 / 欧洲，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、当地大型医药制造及流通企业及公司会谈，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。

二是我会将进一步深化与日本制药协会（JPMA）、韩国生物制药协会（KPBMA）等战略合作伙伴的合作，打造中韩医药产业与投资界合作交流平台，推动亚洲医药创新产业发展，打造中日韩医药产业合作的重要区域性平台，深化亚洲在全球医药创新领域的重要地位。

（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国际化发展的活动。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。

五、继续办好“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，办好一年一度的医药创新与投资大会、溶瘤病毒大会等品牌性活动，并以各分支机构为依托，充分发挥其专业特色，开展糖尿病和代谢性疾病药物器械研发创新大会、医药创新政策论坛等主题丰富形式多样的业务交流活动，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。

六、持续完善分支机构组织架构，不断汇聚高端资源要素，有序推进分支机构成立、换届工作，为促进药械产业跨界交流和创新发展探索新思路、开拓新路径、提供新方法

2025 年，我会将继续完善涵盖大健康产业全链条专家资源的分支机构组织架构，始终坚持以全链条资源为依托，以国际化视野为统领，以临床需求为导向，以解决产业实际需求为抓手，探索分支机构差异化发展新模式，聚焦生命健康板块多个前沿核心领域，为大健康产业全链条各主体搭建资源共享、信息互通、成果互惠、合作共赢的开放性合作平台，为持续推动我国大健康产业高质量创新发展不断贡献新的力量。根据分支机构整体工作计划，2025 年我会拟新设立“细胞与基因治疗专业委员会”，与现有专业委员会共同举办多项业务活动和相关工作会议，全方位推动医疗健康产业创新、可持续、高质量发展。

（一）统筹规划分支机构发展方向，整合资源要素，精准聚焦产业核心需求，为分支机构可持续发展奠定坚实基础

2025 年，我会药物研发、医药政策、医药创新投资、创新研发服务、国际创新药物监管、医药数字化及创新疗法、药物临床试验、心血管药物临床研究、抗肿瘤药物临床研究、脑神经药物临床研究和创新医疗器械专业委员会将根据产业实际情况整合资源要素，动态调整业务方向并完成换届改选相关工作。我会糖尿病与代谢性疾病药物临床研究专业委员会拟延期至 2026 年换届。

（二）充分发挥高端资源集聚优势，为社会各界提供专业的药械产业资讯和信息服务

2025 年，我会抗肿瘤药物临床研究和医药数字化及创新疗法专业委员会将联合国际权威媒体和学术机构，调研访谈顶级专家、产业领袖、专业投资人，适时发布《2024 年度中国抗肿瘤新药临床研究评述》和《人工智能与药物发现产业调研报告》，为我国药械产业研发及投资活动提供参考。

（三）持续推动临床急需药品临床研究和上市后临床试验服务、企业合规伦理准则制修订、生物样本活库标准化建设等项目落地实施。

七、充分发挥智囊智库作用，依托高端产业资源优势，加深与地方政府及相关机构务实合作

我会将继续开拓与地方政府（产业园区）的合作，帮助各级地方政府带来大健康领域专业流量、引入大量药械产业高端创新资源、带动药械领域高质量创新主体集聚效应、协助搭建一批国家级创新转化平台和孵化器，吸引一批高学历专业人才和投资人扎根落户，孕育一批国际领先的创新型企业及品牌，为国家打造现代化的医疗大健康产业集群持续贡献力量！

党的二十大报告明确了科技创新领域 2035 年总体目标和主要任务，对加快实施创新驱动发展战略作出专门部署，坚持四个面向（坚持面向世界科技前沿、面向经济主战场、面向国家重大需求、面向人民生命健康），加快实现高水平科技自立自强。党的二十届三中全会再次提出要健全支持创新药和医疗器械发展机制，体现了国家对医药创新产业支持发展的决心和坚定意志。

生物医药作为科技创新领域的重要产业，深刻影响民众福祉。2025 年是“十四五”规划的收官之年和攻坚阶段，同时也是为“十五五”规划奠定基础的关键时期。新的一年，中国药促会将进一步加强与政府部门的沟通交流，为完善创新药和医疗器械的相关政策法规建言献策；积极搭建产学研用医合作平台，促进高校、科研机构、企业和资本之间的深度合作，加速科技成果转化，实现创新资源的优化配置和高效利用；加强与国际医药组织、企业、科研机构的交流合作，积极参与国际规则制定，提升中国在全球医药领域的话语权和影响力，为中国医药产品走向国际市场创造有利条件。2025 年，中国药促会将继续发挥桥梁纽带作用，和会员单位一道，抓住机遇，迎接挑战，为实现我国生物医药产业的高质量发展和创新升级，为增进民众福祉和健康中国建设作出更大的贡献。

2024 Annual Work Report & 2025 Work Proposal

In 2024, amid intertwined opportunities and challenges, the biopharmaceutical industry continued to forge ahead. China Pharmaceutical Innovation and Research Development Association (PhIRDA) has remained committed to its missions and proactively fulfilled its responsibilities. Furthermore, in terms of promoting policy refinement, it has engaged in in-depth research on the challenges and pain points faced by the pharmaceutical and medical device industries, proposed timely policy recommendations, and assisted members in addressing practical issues. In strengthening international exchange and collaboration, PhIRDA has collaborated extensively with domestic and international pharmaceutical associations, enterprises, and research institutions, and has established platforms for global dialogue and promoted multifaceted cooperation in the pharmaceutical sector. In driving industry innovation, it has aligned itself with the national innovation-driven development strategy, expanded financing channels for pharmaceutical innovation, fostered a more attractive investment environment, and enabled collaborative opportunities for members. With such efforts, PhIRDA has achieved remarkable progress in multiple aspects, and made significant contributions to the advancement of the biopharmaceutical industry in China. The main tasks completed by PhIRDA in 2024 and recommendations for the efforts in 2025 are reported as follows:

Part I. Review of Major Work in 2024

I. Strengthen the Theoretical Foundation, Leading PhIRDA Forward with Party Building as the Core

The Party branch of PhIRDA has always adhered to Xi Jinping Thought on Socialism with Chinese Characteristics for a New Era as its guide, comprehensively implemented the spirit of the 20th National Congress of the Communist Party of China and the Second and Third Plenary Sessions of the 20th Central Committee of the Communist Party of China, steadily promoted the standardization and normalization of the Party branch, continuously upgraded the quality of Party building efforts, and guided the high-quality development of PhIRDA through Party building. Efforts have been made to focus on ideological and political construction, adhere to the "Top Priority" system, closely follow up on the study and implementation of General Secretary Xi Jinping's important speeches and instructions in a timely manner; to solidly engage in learning and education about Party disciplines in accordance with the requirements under unified deployment of the CPC Committee of National Industry Associations and Chambers of Commerce as well as the CPC Committee of the China Federation of Industrial Economics, further raise the awareness of disciplines among Party members in the Party branches, and educate and guide Party members and cadres in studying, understanding, upholding and abiding by the Party disciplines; to reinforce organizational building, meticulously plan and organize the implementation of theme Party Day activities in a variety of forms while strictly implementing the "Three Meetings and One Class", and, through diverse practices and learning, enhance the cultivation of the Party spirits among all Party members. In accordance with related regulations on the admission of new Party members, during the reporting period, two probationary Party members of the Party branch of PhIRDA have become full members of the Party, and two active candidates for Party Membership have been approved.

II. Propose Recommendations and Initiatives to Several Central Ministries and Commissions to Promote the Whole-Chain Supportive Pharmaceutical Innovation Policies by Fully Leveraging the Advantages of the High-End Think Tank

(I) Uphold new development concepts, focusing on the contradictions and problems of innovative development, submitting recommendation reports to related national ministries and commissions, to promote high-quality development of the industry.

In the current context of the biopharmaceutical innovation and development strategy and the concept of New Quality Productivity, PhIRDA has submitted the *Report on Supporting Policies for the Development of Innovative Drugs* to the Central Committee of the Chinese Peasants and Workers Democratic Party to promote the integration of medical production, research and application by strengthening policy coordination, expedite the cultivation of a competitive innovation system and ecological environment, and inspire the vitality and momentum of original innovation. As commissioned by the Department of Comprehensive System Reform, National De-

velopment and Reform Commission (NDRC), PhIRDA has engaged in thematic research on the New Quality Productivity, and has organized multiple seminars and research studies, resulting in the *Research on Addressing Blockages and Bottlenecks in the Full Chain of Biopharmaceuticals Innovation to Promote New Quality Productive Forces,* with the aim of promoting the establishment of a new type of relationship among government bodies, medical institutes, research institutes, users and investors aligned with innovative development.

In the context of the promulgation of the *Pilot Implementation Plan for Comprehensive Reform in Pudong New Area (2023-2027)* by the Central Government, which explicitly supports Pudong New Area in building a leading area of socialist modernization, PhIRDA has submitted the *Suggestions and Measures for Promoting the Implementation of the Pudong New Area's Pilot Comprehensive Reform* to the People's Government of Pudong New Area, Shanghai, proposing initiatives related to "allowing the pricing of new biopharmaceutical products to be determined with reference to similar international drugs", for the purpose of promoting the implementation of related policies for a pricing system that is in line with international standards as soon as possible.

Meanwhile, PhIRDA has been invited to attend the 7th Session of the Standing Committee of the 14th National Committee of the Chinese People's Political Consultative Conference and the 27th Biweekly Consultative Symposium of the 14th National Committee of the Chinese People's Political Consultative Conference, proactively proposing recommendations for the innovative development of the pharmaceutical industry.

(II) Closely focus on coordinating industrial innovation and development in policy formulation and implementation, promoting consistency in policy orientation among various departments, and addressing the urgent demands and expectations of the industry.

First, attach great importance to the impact of drug pricing policies and proactively voicing the pain points and demands of the industry. PhIRDA has paid visits to the Department of Drug Prices and Procurement of National Healthcare Security Administration, participated in the symposium on the guidelines for the initial pricing of newly launched chemical drugs, communicated the concerns and demands of the industry, championed the independent pricing right, and safeguarded the legitimate rights and interests of innovators. Furthermore, through discussions at the Eighteenth Meeting of the 11th Board of Directors, PhIRDA has formulated related recommendations for the *Establishment of a Pricing Mechanism for Newly Launched Chemical Drugs to Encourage High-Quality Innovation (Draft for Comments)* and provided feedback to the National Healthcare Security Administration.

Second, refine national drug policies and promoting collaborative governance of the "Tripartite Medical System" (Healthcare, Insurance, Pharmaceuticals) and innovative drug development. As commissioned by the Department of Drug Policy and Essential Medicine System of the National Health Commission, PhIRDA has launched a thematic research on national drug policies, and has formulated the thematic research report entitled *Focusing on Enhancing the Clinical Benefits of New Drugs and Promoting the Systematic Construction of Policies for the Whole Drug Chain,* with a view to promoting the coordinated linkage of multiple authorities such as the National Health Commission, the National Development and Reform Commission, the Ministry of Science and Technology, the Ministry of Industry and Information Technology, the National Medical Products Administration, and the National Healthcare Security Administration, and facilitating the formation of policy synergies through the alignment of industrial, technological, financial, healthcare, medical, and pharmaceutical policy orientations, thereby providing a reference for improving the national drug policy system.

Third, deepen institutional mechanism reform, continuously promoting the capacity building and system reform of drug and medical device regulation in China. PhIRDA has held seminars for member enterprises to discuss related issues such as registration and production that the industry faces. It has submitted the *Suggestions on Deepening Drug Registration Review Process to Promote Pharmaceutical Innovation and Industry Development* to the Center for Price Cost Investigation and Authentication under the National Development and Reform Commission, with the aim of optimizing the allocation of review resources and improving service efficiency. It has also submitted reports on research results such as the *Proposal Report on Continuing to Deepen Drug Regulatory Reform and the Report on China's Innovative Medical Device Review System Reform* to the National Medical Products Administration.

Fourth, extensively convey industry demands to related government authorities and calling for greater attention to the development of the pharmaceutical innovation industry. PhIRDA has collaborated with the Department of International Economic Affairs under Ministry of Finance in engaging in policy research discussions on "Issues

Related to Innovative Drug Industry Development", and has assisted the Center for Price Cost Investigation and Authentication under National Development and Reform Commission (NDRC) in organizing informal discussion for the surveying of "Drug Registration Fee Situation". Furthermore, it has also participated in thematic research and discussions on the bio-economy hosted by the Innovation Center under NDRC, and has submitted a report titled *Report on Challenges and Recommendations for Pharmaceutical Innovation Ecosystem and Trade Policies in China* to the Department of Foreign Trade, Ministry of Commerce.

(III) Sustain Commitment to Medication Access for Rare Disease Patients

PhIRDA has closely followed national regulatory frameworks and performed in-depth analyses of challenges faced in industry development and at different stages such as clinical practice and patient care. Furthermore, it has provided multidisciplinary perspectives and strategies to construct a legal framework for rare diseases, promote the R&D of drugs for rare diseases, and optimize patient diagnosis and treatment, etc., with a view to strengthening the supply and guarantee capabilities of drugs for rare diseases throughout the whole chain.

III. Track Industrial Development Trends, Undertaking High-Quality Research Projects, and Facilitating the Continuous Improvement of the Policy and Market Environments for Medical Innovation

(I) Focus on in-depth integration of the whole industry chain of "production, learning, research and medical care"; undertaking government-commissioned projects; propelling close integration of clinical practice and scientific research and innovation; and creating a virtuous closed loop of innovation.

As commissioned by the Beijing Municipal Health Commission, PhIRDA has undertaken the "Dynamic Evaluation of Model Research-Oriented Ward Construction in Beijing" on an ongoing basis, with the aim of promoting construction through evaluation. Furthermore, it has fine-tuned the research-oriented ward evaluation index system based on the problems identified during the preliminary evaluation and recent researches, and convened expert forums to further revise and improve the index system. PhIRDA has objectively evaluated the development outcomes of model units in infrastructure development, clinical research capabilities, and achievement transformation for research-oriented wards, and has summarized the three-year progress of the second batch of research-oriented wards, while systematically organizing the phased achievements of the third batch. And such efforts have resulted in a comprehensive evaluation report with actionable policy-based recommendations. PhIRDA has concurrently launched a solicitation initiative for best practices targeting 30 model units in three batches, and has compiled the Exemplary *Case Compendium for Research-Oriented Wards*.

(II) Launch Research Projects to Address the Pain Points and Bottlenecks in Industry Development, with a View to Continuously Improving the Development Ecology of Industrial Innovation and Internationalization.

First, under the leadership and guidance of the National Medical Products Administration (NMPA) and the Center for Medical Device Evaluation under the NMPA, PhIRDA has launched the work of "Research on the Reform of China's Innovative Device Review System", with a focus on the review and management system and mechanism of medical devices and the issues that restrict the innovation and development of the industry. In-depth research has been initiated with a view to establishing a national unified, efficient and scientific review and supervision system, improving review and supervision capabilities, promoting the modernization of supervision, and promoting the high-quality development of the innovative device industry in China. Meanwhile, it is expected to provide suggestions and references for the legislation of the *Medical Device Administration Law of the People's Republic of China* and the reform of the review system.

Second, PhIRDA has initiated the "Study on the Technical Pathway for China's Innovative Drugs Going Global" to assist China's innovative drugs in exploring the international market along the Belt and Road. Furthermore, it has recommended the strengthening of inter-departmental collaboration at the strategic level and the construction of a collaborative network with overseas regulatory authorities. Meanwhile, from the perspective of industrial development, PhIRDA has proposed the establishment of a whitelisting mechanism, prioritization of domestic innovative medicines in foreign aid medical treatment, encouragement of global multi-regional clinical trial (MRCT), promotion of international exchanges and cooperation among industries, etc., with a view to enhancing the international recognition and international visibility of domestic innovative medicines.

Third, PhIRDA has conducted the "Research on Pricing Mechanisms for Innovative Drugs in the Context of Internationalization", with a view to analyzing the pricing rules and mechanisms of innovative drugs in the mainstream international market, and has proposed related recommendations

on the establishment of a market-driven drug pricing mechanism from the perspective of perfecting the market mechanism, with a view to reducing undue government intervention and assisting local innovative enterprises in standing out on the international stage while establishing a foothold in the domestic market.

Fourth, PhIRDA has launched "Research on an Innovative Payment System Based on Patient Payment Prices and Medical Insurance Payment Prices", with a view to enhancing the payment security for original innovation. Such efforts aim to break through the payment dilemma of high-value innovative drugs, explore the establishment of an innovative payment model integrating the price paid by health insurance and the price paid by patients in China, and propose the "ABC Co-payment Model", thereby promoting the accessibility and international competitiveness of high-value innovative drugs.

Fifth, under the guidance of the Beijing Municipal Commission of Health, PhIRDA has joined hands with related organizations (Beijing Pharmaceutical Association, clinical trial institutions in Beijing, and R&D-Based Pharmaceutical Association Committee (RDPAC)) to launch a series of research projects on "Research on the Improvement of Clinical Trial Efficiency", and has formed and released the *The Beijing Consensus on Drug Clinical Trial Contracts,* thereby contributing to the improvement of the innovation capabilities of Beijing and even the whole country.

IV. Participate in Learning and Revision and Formulation of Important Policies and Regulations, and Promoting the Improvement of the Policy Framework

(I) Participate Intensely in the Improvement of Legal and Regulatory System Construction and the Research on Deepening of the System

First, PhIRDA has attached great importance to the construction of the rule and law for medical devices, and has intensively engaged in the discussion and consultation of the legislation of the *Medical Device Administration Law of the People's Republic of China.* The promulgation of the *Medical Device Administration Law of the People's Republic of China,* as an important and top-level design document, should not only serve as a confirmation of the existing supervisory and management system, but also be forward-looking and systematic. PhIRDA has convened enterprise symposiums and launched related researches in a timely manner, and paid a visit to the Center for Medical Device Evaluation under the National Medical Products Administration and the Department of Registration under the National Medical Products Administration for face-to-face communication and exchanges on the obstacles facing the development of innovative industries, the reform of the evaluation system mechanism, etc. Furthermore, it has presented related recommendations to the *Medical Device Administration Law of the People's Republic of China (Draft for Comments),* with a view to further detailing the reform of the review and approval system of medical devices, and contributing to providing legalization guarantee for the establishment of a unified, standardized, efficiently managed and authoritative national regulatory system for medical devices.

Second, PhIRDA has participated in seminars on basic systems and regulations to improve the institutional system of supervision and control. PhIRDA has been invited to participate in the seminars related to the *Special Provisions on the Management of Traditional Chinese Medicine Standards (Draft for Comments)* organized by the National Medical Products Administration, with a view to promoting the construction of the standard management system of traditional Chinese medicine in compliance with the characteristics of traditional Chinese medicine; and has submitted the related suggestions on the *Announcement on Matters Relating to Further Optimization of the Review and Approval of Overseas Listed Drugs in Urgent Clinical Needs,* with a view to further expediting the process of increasing the efficiency to satisfy the demands of medical institutions for the use of drugs in clinical settings, etc.

(II) Establish a platform for communication between the government and enterprises and broadening the channel for cooperation between the government and enterprises.

As commissioned by CDE, PhIRDA has assisted in the development of the catalog of 2024 guidelines, customer satisfaction surveys, the collection and feedback of related opinions on drafting, etc. Furthermore, it has proactively organized and recommended members to deeply participate in the formulation and revision of related guidelines including the *Pilot Program of Patient-Centered Drug R&D for Rare Diseases* (hereinafter referred to as the "Care Program"), CAR-T cell therapy products, clinical R&D of drugs for treatment of HIV incomplete immune reconstruction, clinical pharmacology of peptide drugs, and pharmacovigilance.

V. Actively Broaden Channels for Voices, Increasing Industrial Influence

First, focusing on issues of concern to the industry, PhIRDA has organizing seminars and exchanges with enterprises. For example, the exchange conference of the

National Health and Wellness Commission on promoting the construction of the drug supply guarantee system under the coordination of the Tripartite Medical System, the symposium of the China Center for International Economic Exchanges on optimizing the pricing mechanism of innovative drugs, the symposium on improving the negotiation system of the medical insurance catalog in China, as well as the symposium on optimizing the drug regulatory policies. Furthermore, based on the absence of specific regulations for the drug data protection system and the subsequent healthcare access challenges faced by the absence of a separate registration pathway for natural medicines, PhIRDA has gained an in-depth understanding of the actual problems faced by the enterprises, and has submitted a recommendation report to competent authorities in the industry, such as the National Medical Products Administration and the National Healthcare Security Administration.

Secondly, PhIRDA has compiled and summarized the results of industrial development and research, published academic articles and research reports, and provided theoretical references and empirical evidence for the formulation and improvement of policies. Two studies have been included in book publication and four journal articles have been separately published. PhIRDA has published *Ecosystem Development and Investment Opportunities in Translational Medicine* (in a separate chapter) in the book series of *Report on Precision Medicine: Research Innovation and Industrial Development,* which was honored as "Outstanding Medical Book of Tsinghua University Publishing House for 2024", and the *Regulatory Capacity Building and Regional Industrial Upgrading Under the MAH System - Summary of Yangtze River Delta Region Experience* has been included in *Frontier Research in Drug Administration (2023),* etc.

Forty Years of Changes and Thinking on China's Drug Regulation has been published in *China Pharmacy, Research on Innovative Multi-Payment System to Promote the Access and Implementation of High-Value Innovative Drugs* has been published in *China Health Insurance, Reflections on the Reform of Review and Approval System of Medical Devices in China and Overview of WHO Regulatory Assessment System and Reflection on the Internationalization of China's Drug Regulation* has been published in *China Food and Drug Regulation Magazine.*

VI. Deeply conduct international pharmaceutical exchanges and promoting 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 promoting the implementation and transformation of ICH guidelines in China.

First, as a member of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), PhIRDA has recommended 60 experts (including 11 Lead Experts and 9 Alternates) to 29 ICH Expert Working Groups (EWGs) of the IFPMA since 2017. During the reporting period, the experts recommended by PhIRDA accounted for over 37% of the total number of IFPMA experts globally.

Second, as commissioned by the ICH Office of NMPA, PhIRDA has solicited opinions from PhIRDA members and timely fed back industry opinions on 71 ICH guidelines with a view to promoting the smooth implementation of ICH guidelines in China. Furthermore, as commissioned by the CDE, PhIRDA has actively recruited experts for ICH Expert Working Groups. During the reporting period, 130 experts recommended by PhIRDA have been included in 39 CDE ICH Expert Working Groups.

Third, PhIRDA has invited multiple industry experts to perform in-depth interpretation and sharing on topics, such as electronic application for drug registration as well as eCTD implementation strategy, analytical method validation/analytical method development, etc., with a view to assisting enterprises in better adapting to ICH guidelines having been and about to be implemented.

Fourth, PhIRDA has organized more than 20 members to cooperate with CDE to carry out trial tests on the network transmission of eCTD for several times, laying a foundation for the successful development and full implementation of eCTD.

Fifth, the four IFPMA ICH experts recommended by PhIRDA have participated in the related working meetings of the Working Groups on M11, Q6(R1), Q2/Q14 and E2D(R1) in the ICH Assembly held offline respectively in Fukuoka, Japan, and Montreal, Canada in June and early November 2024 respectively, which have made significant contributions to accelerating the harmonization and unification of the regulatory rules, promoting the mutual recognition of the international regulation and co-promoting the development of the global pharmaceutical industry.

(II) Establish a platform for cooperation and exchange between the pharmaceutical industry and investment communities in China and South Korea, driving the development of the pharmaceutical innovation industry in Asia, building an important regional platform for communication in the phar-

maceutical industry, and deepening the important position of Asia in the field of global pharmaceutical innovation.

Zhang Shuyang, Chairman of PhIRDA, and Song Ruilin, Executive President of PhIRDA, have had two productive meetings with Mr. Yunhong NOH, President of Korea Pharmaceutical and Bio-pharma Manufacturers Association (hereinafter referred to as the "KPBMA"), and Mr. Lee Hyun-woo, Vice President of KPBMA, and have engaged in in-depth exchanges on the promotion of the cooperation between China and South Korea on the medical innovation industry. Based on the shared objective of building a platform for the cooperation of the pharmaceutical industry between China and South Korea, PhIRDA has signed a Memorandum of Understanding with KPBMA, in which both sides will establish a regular cooperation and exchange mechanism and exchange visits on a regular basis, launch the cooperation between the pharmaceutical industry between China and South Korea, broaden the cooperation of investment in China and South Korea, join forces to promote the cooperation between the governmental regulatory agencies of China and South Korea, liberalize the markets of both sides, and facilitate the entry of pharmaceutical products into the markets of the two countries, and the two associations will take turns to host the Innovation Conference of the Pharmaceutical Industry between China and South Korea to jointly promote the construction of the innovation ecosystem of the pharmaceutical industry in Asia and to expand the in-depth cooperation in the pharmaceutical field among China, Japan, and South Korea.

(III) Strengthen cooperation and exchanges with European regulatory authorities and pharmaceutical industry associations, promoting the innovative development of the biopharmaceutical industry in China, Europe and the world to benefit patients worldwide.

Dr. Song Ruilin has had a friendly meeting with Barbara Goezinne, Vice Minister of Health Services of the Ministry of Health, Welfare and Sport of the Netherlands, in Beijing on June 24, 2024. Both sides have reached a consensus on the promotion of cooperation between China and the Netherlands in terms of pharmaceutical supervision and industry, to jointly promote the establishment of a unified regulatory standard for medicines by the pharmaceutical regulatory authorities of both countries, to shorten the review and approval cycle, reinforce the exchanges and cooperation in the field of clinical areas and the problem of shortage of medicines, facilitating the mutual exchange and communication of medicinal products between the two countries.

Dr. Song Ruilin has had a friendly meeting with Lars Fruergaard Jørgensen, President of the European Federation of Pharmaceutical Industries and Associations (EFPIA), President and CEO of Novo Nordisk, and signed a Memorandum of Understanding on 11th, September, 2025 in Beijing. The meeting has laid a solid foundation for long-term and stable cooperation between the two sides in biopharmaceutical industry. Both sides will give full play to the advantages of resources and platforms, with a focus on cooperation in drug R&D, supervision, intellectual property rights and data protection, etc., for the purpose of realizing the sharing of resources and complementing advantages of each other, expediting drug marketing between China and Europe, and promoting the high-quality development of the pharmaceutical industry in both China and Europe.

With the rapid development of biotechnology, Europe has become a preferred partner for pharmaceutical industry cooperation of China, and it is also the region where PhIRDA will focus on international cooperation. The in-depth cooperation with the related health authorities in the Netherlands and EFPIA is expected to positively contribute to the promotion of innovation and development of the biopharmaceutical industry in China, Europe and even the world, and to benefit patients worldwide.

(IV) Conduct exchanges with and visits to embassies and consulates, industry associations, and international organizations in various countries, sharing the achievements of China's drug regulation, promoting international industrial exchanges, and promoting win-win cooperation in the global pharmaceutical industry.

PhIRDA has always actively explored new cooperation opportunities and developed new partners in international affairs, and maintained close contact with the embassies and consulates and related institutions of countries including the United States, Canada, the United Kingdom, Australia, Japan, the Netherlands, Denmark, Spain, Switzerland, Finland, Italy, Belarus, Uzbekistan, Turkmenistan, Israel and Singapore, as well as international organizations such as IFPMA and APAC to jointly promote mutual exchange and cooperation in the global pharmaceutical industry.

Upon invitation, PhIRDA has attended international conferences including the 12th Asia Regulatory Conference (ARC), the 4th Asia Summit on Global Health (ASGH), Zhi-xing China - Perfect World US-China Young Leaders Fellowships, and Closed-Door Symposium on China-Sweden Pharmaceutical Innovation Industry, fully demonstrating 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.

(V) Establish an empowerment platform for innovative Chinese products to go global and enabling China's innovations to benefit more patients worldwide.

Upon the invitation of related government authorities of the Kingdom of Saudi Arabia (hereinafter referred to as "Saudi Arabia"), PhIRDA has organized a delegation of Chinese innovative pharmaceutical and medical device enterprises for official exchanges in Riyadh, the capital city of Saudi Arabia, during November 9-13, 2024, to conduct seminars and on-site visits with the health, regulatory authority, investment, procurement, clinical research institutions and local pharmaceutical and medical device enterprises in Saudi Arabia. Furthermore, it has facilitated the financing and landing of Chinese pharmaceutical enterprises in the Middle East, established an empowerment platform for innovative Chinese products to go global and enabled China's innovations to benefit more patients worldwide.

(VI) Invited to contribute an article in the international media PharmaBoardroom to demonstrate the achievements of China's drug regulation reform and pharmaceutical industry innovation to the world.

Dr. Song Ruilin and leaders of several members in innovative medicine have been interviewed by PharmaBoardroom, which has been formally published in the *Healthcare & Life Sciences Review China 2024,* demonstrating the important position of China in the field of global biopharmaceutical, and especially the remarkable achievements in innovative drug R&D, industrialization as well as international cooperation.

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

In recent years, by virtue of the profound experience and remarkable influence within the industry, PhIRDA has organized and planned multiple key projects such as the China BioMed Innovation and Investment Conference, and, by fully leveraging the professional advantages of its branches and integrating the resources of experts in different fields, PhIRDA has organized a series of highly professional and branded events such as the Pharmaceutical Innovation Policy Forum to provide diversified solutions to satisfy the demands of the pharmaceutical and equipment industry.

(I) China BioMed Innovation and Investment Conference

From November 30 to December 1, 2024, PhIRDA, jointly with other organizations such as the HKEX, organized the 2024 China BioMed Innovation and Investment Conference, which was successfully held in Guangzhou, China. The Conference was held in Guangzhou for the first time. Leveraging the policy and regional advantages of the Guangdong-Hong Kong-Macao Greater Bay Area, it featured the theme centered on "Integrating Pharmaceutical Industry and Capital for Innovation, Stimulating the Source Technological Innovation Vitality of China's Pharmaceutical Innovation Entities, and Shaping a High-Quality Development Environment for Pharmaceutical Innovation." The event invited stakeholders across the entire pharmaceutical and medical device industry chain. It focused on global economic trends and forms of cooperation, as well as commercial insurance policies. Additionally, discussions covered investment and M&A, licensing, and commercialization, and key topics also included the internationalization of new drug R&D regulations and clinical research collaboration. Cutting-edge technologies, such as cell and gene therapy, were highlighted as well. The Conference aimed to address industry hot topics and satisfy the diverse demands of all participants, and organized nine professional forums and featured on-site roadshows for over 80 innovative projects, attracting nearly 2,000 participants, creating a platform for resource sharing, information exchange, and mutually beneficial cooperation. The event facilitated more than 500 business negotiation sessions, so as to satisfy a wide range of collaboration demands, receiving widespread acclaim from the industry.

(II) Interdisciplinary Oncolytic Virotherapy Innovation Convention

To further advance the clinical development of oncolytic virus drugs and promote comprehensive communication and collaboration across the oncolytic virus field, the Second Interdisciplinary Oncolytic Virotherapy Innovation Convention, guided by PhIRDA and the Administrative Committee of Wuhan East Lake High-Tech Development Zone, was held during October 26-27, 2024 in Wuhan, Hubei Province. The event featured seven thematic forums: Early R&D-Process and Safety Assessment, CMC Research, Clinical Research, Commercialization and International Collaboration, Industry Standard Setting, Basic and Clinical Translation, and Rare Diseases. Participants from industry, academia and investment circles both at home and abroad were invited to share the interpretation of regulations and policies in the field of approval and regulation of lysosomal viruses, the current situation of R&D

in the industry and scientific research achievements, and to explore approaches to address the new opportunities and challenges of the domestic and international innovative drug environment.

(III) Hefei Biopharmaceutical Innovation & Industry Conference

During September 6-7, 2024, the Second Hefei Biopharmaceutical Innovation & Industry Conference, jointly organized by PhIRDA and the Institute of Health and Medicine, Hefei Comprehensive National Science Center, and the Office of Hefei Comprehensive National Science Center, Office of the Anhui Provincial Life and Health Industry Promotion Group, etc., was grandly held in Hefei. The event organized more than ten forums, roadshows, invited more than 100 scientists, entrepreneurs, clinical researchers, professional investors and nearly 1,000 professional visitors to participate in the conference, with a focus on the frontiers of biopharmaceuticals, focusing on the hotspots and difficult issues in the research, development, industrialization and regulation of innovative drugs, such as antibody drugs, cellular therapeutic drugs and gene therapeutic drugs to explore the technological ecology and envision the new future of industrial cooperation and development.

(IV) "Star of the Greater Bay Area" Biopharmaceutical Original Innovation Forum

On December 3, 2024, the 2024 First "Star of the Greater Bay Area" Biopharmaceutical Original Innovation Forum, hosted by PhIRDA, was held in Shenzhen. With a focus on "Activating the First Kilometer of Original Innovation", the event invited leaders from related state leaders and leaders from government authorities, top scientists of the world, global clinical research leaders, renowned investors in the field of investment and financial services, as well as leaders of the pharmaceutical and equipment industry. From the scientific discovery, scientific transformation, investment and incubation, enterprise empowerment, policy guidance, etc., discussions were held on the key points and paths of original innovation, and shared with the audience on approaches to escape from the industrial "involution" dilemma, and stimulate innovation momentum for industrial growth.

(V) China Innovation Conference on Diabetes, Metabolic Diseases and Medical Devices R&D

During April 27-28, 2024, the 2nd China Innovation Conference on Diabetes, Metabolic Diseases and Medical Devices R&D, co-hosted by PhIRDA Specialty Committees on Clinical Research on Diabetes and Metabolic Diseases Drugs, was held in Chengdu. The event featured ten theme forums, which invited authoritative physicians, policy experts and business leaders in the field of diabetes and metabolic diseases, with a focus on the key points and difficulties of drug and device innovation in the field of diabetes and metabolic diseases, which closely centered on the clinical demands, and discussed in-depth the innovative R&D solutions.

(VI) China Pharmaceutical Innovation Policy Forum

On June 21, 2024, the 2024 China Pharmaceutical Innovation Policy Forum hosted by PhIRDA was held in Shanghai. Centered on the two themes of "Discussion on the Implementation Initiatives of the 'Pudong Program'" and "Innovative Payment System", the event presented a high-quality event with the audience focusing on pharmaceutical innovation, expert cooperation, policy analysis, and judgment of future industry trends.

(VII) Pharmaceutical and Medical Device Industry Digital Intelligence and Biotechnology Innovation Conference

On October 12, 2024, the Pharmaceutical and Medical Device Industry Digital Intelligence and Biotechnology Innovation Conference, co-sponsored by PhIRDA Digital Medicine and Innovative Therapy Specialty Committee and Innovative Medical Devices Specialty Committee, was held in Suzhou, focusing in depth on topics including innovation policy of the pharmaceutical and device industry, innovative technology research and development, and modern information technology applications, with a view to leveraging cross-boundary cooperation and fusion of development among digital technology, financial capital and the medical device industry.

VIII. Continuously pool high-end resources and elements, promoting the high-quality development of branches, fully leveraging the role of branch experts and think tanks, and contributing to the promotion of high-quality and sustainable development of the medical device industry of China

Since the conclusion of the Eighteenth Meeting of the 11th Board of Directors on February 22, 2024, PhIRDA has relied on the resource advantages of branch experts and members to launch a great deal of fruitful efforts in the seven major areas including R&D of medical devices, clinical research, policy research, international exchanges and cooperation, investment and financing, digitalization of medical devices and compliance, etc., which have been widely concerned and highly acclaimed by all sectors of the society. In accordance with the related provisions of the administrative measures of PhIRDA on the branches, in August 2024, PhIRDA made a comprehensive supplement to the members of the branches. Following a rigorous member recommendation and selection process, a total of 105 new members have been added, of

which 18 are from the IFPMA ICH Task Forces members. Upon the completion of the replenishment, there are a total of 832 members in the 13 branches of PhIRDA, adding fresh energy for the branches to engage in follow-up work.

(I) Maintain close contact with related authorities of the national government, proactively participating in the formulation and revision of laws and regulations related to the upstream and downstream of the entire pharmaceutical and equipment industry chain, and speaking out on behalf of the main body of medical device innovation.

First, PhIRDA Specialty Committees on Pharmaceutical Policy, Innovative Medical Devices, Digital Medicine and Innovative Therapy, Clinical Trial Research, and Ethics and Business Compliance have actively participated in the formulation and revision of many laws, regulations and guidelines of related government authorities, and have resulted in a number of research results and policy recommendation reports. The related comments and recommendations have been adopted.

Second, on December 2024, PhIRDA Specialty Committee of Drug R&D and Pharmaceutical Innovation Investment organized representatives of biotechnology enterprises, investment institutions and service providers and other participants in the Hong Kong capital market to conduct discussions and exchanges around the system related to the Hong Kong Stock Connect, and developed the *Proposal on Improving the Policies Related to the Hong Kong Stock Connect* for submission to the China Securities Regulatory Commission (CSRC).

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

On August 31, 2024, the PhIRDA Clinical Research on Oncology Drugs Specialty Committee, jointly with Beijing CSCO Clinical Oncology Research Foundation, etc., released the *2023 Review of Clinical Research on New Anti-tumor Drugs in China,* and convened the Conference on the Clinical Research of Anti-tumor Innovative Drugs, with a view to guiding the scientific, rational, and orderly development of drug R&D.

(III) 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.

Since 2020, PhIRDA and the PhIRDA Clinical Research on Cranial Nerve Drugs Specialty Committee have joined forces with members, Beijing Tiantan Hospital, BeOne Medicines, CR Double-Crane, Betta Pharma and Sanhome to launch the Post-market Clinical Observation and Re-evaluation Service Program, with a view to contributing to the satisfaction of the clinical demands of patients for medication.

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

To adapt to the latest changes in the related legal regulations and international standards in the field of compliance, the Specialty Committee on Compliance of Pharmaceutical Enterprises under PhIRDA, in conjunction with the RDPAC, has engaged in the work of revising the *Code of Ethics for Pharmaceutical Enterprises,* with a view to promoting the harmonization of the compliance standards of different industrial entities and convergence with the international standards thereof.

(V) Build a standardized, high-quality biospecimen living biobank to significantly guarantee translational medicine.

In 2024, PhIRDA Specialty Committees of Clinical Research on Oncology Drugs, Innovative R&D Services and Ethics and Business Compliance have jointly launched an expert consensus on the establishment and standardization of quality management system for clinical biospecimens, and invited experts in the industry to participate in the preparation, revision and release of the expert consensus on the construction and management of biospecimen biobanks, with a view to providing reference for the establishment and standardization of quality management system for clinical biospecimens.

IX. Fully leverage the advantages of industrial resources, establishing close connection with relevant local departments and professional institutions, deepening business linkage with local governments and industrial parks, and jointly serving 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 multiple parties including local governments, industrial parks, research institutions, colleges and universities, industries, capital, and service companies, and has conducted a great deal of research and basic efforts on pattern to assist local governments and industrial parks in introducing innovative resources for the pharmaceutical industry, revitalize the stock of space for the development of the pharmaceutical industry, and extend the space for incremental development. Since 2024, PhIRDA has maintained close contact with local governments in Shanghai, Guangzhou, Hefei, Chengdu, Suzhou, etc. and signed strategic cooperation agreements, thereby contributing intellectual support to assist local governments and related industrial parks in building world-class

high-tech parks and modern biopharmaceutical manufacturing clusters with concentrated innovative talents, innovative subjects, innovative results, innovative vitality, as well as an exceptional innovative environment.

X. Adhere to the service concept of "demand-oriented for members", intensifying the research efforts and frequency of members, improving the member service mechanism and system, and strengthening the "sense of acquisition" and cohesion of members.

To pool the power of diversified innovation, PhIRDA has proactively explored the outstanding innovation subjects, optimized and improved the membership structure, and forged an ecosystem for pharmaceutical innovation. Upon voting among the Board of Directors, by the end of 2024, PhIRDA has recruited a total of 15 new members, bringing the total number to 181. These members span the entire industry chain covering the entire industry chain such as pharmaceutical enterprises, medical device enterprises, research institutes, clinical research institutions, innovation service institutions, and pharmaceutical investment institutions.

In 2024, PhIRDA has organized and held several regional member exchanges in Shanghai, Hangzhou, Yantai, etc., in conjunction with the hot topics in the industry and the strategic development of the company, led by the leaders of PhIRDA and joint with industry experts, in-depth visits to 13 members for survey and research.

Meanwhile, PhIRDA has proactively responded to the service demands of its members, continued to fully leverage the advantages of resource integration and the role of the platform window, actively communicating and deepening exchanges and cooperation, and continuously improving the quality of member services by organizing a series of initiatives including brand meetings, opinion collection, and government-enterprise seminars with a view to realizing the demands and suggestions of the members and assisting the government, medical, industry, academia, research, and capital interconnection and interoperability. Furthermore, it has provided members with various member services including brand publicity, information promotion and cooperation resource docking by setting up a column on member dynamics and optimizing the communication and dialogue mechanism, thereby assisting the high-quality development of members at different stages through practical actions.

XI. Fulfill social responsibilities and continuously promoting the Aid for Tibet

From August 14 to 18, the activity "Healthier Tibetans: 2024 Academicians and Experts Free Diagnosis", hosted by Tibet Development Fund (TDF) was held in Lhasa and Shigatse. PhIRDA has organized its members to donate the necessary medicines to the charity clinic, receiving a positive response and active participation from its members. Members such as Hengrui Medicine, Qilu Pharmaceutical, Shanghai Pharmaceuticals, Luye Pharma, Salubris and Yabao Pharmaceutical donated medicines for charity.

Part II. Proposal for Key Work in 2025

I. Under the guidance of Xi Jinping Thought on Socialism with Chinese Characteristics for a New Era, comprehensively implementing the spirit of the 20th Party Congress, and leading the high-quality development of PhIRDA with high-quality Party building

In the upcoming year, PhIRDA will continue to adopt Xi Jinping Thought on Socialism with Chinese Characteristics for a New Era as the guidance of the work of PhIRDA, and as the "master key" for researching and addressing problems. Efforts will be made to reinforce political construction, and to deeply understand the essence of General Secretary Xi Jinping's important speeches and instructions by organizing lectures, exchange seminars, on-site research, etc., so as to make it possible to learn, think, and use in a coherent manner, and to unify knowledge, beliefs, and actions. Efforts will also be made to strengthen organizational construction, innovate the form and content of Party building activities, strictly enforce the systems of organizational life including "Three Meetings and One Class", organizational life meetings, and theme party days, and continuously enhance the cohesion and combat effectiveness of Party branches, making them a strong battlefield for the work of PhIRDA. Meanwhile, PhIRDA will strengthen the construction of style and discipline, enhance the education and management of Party members, base itself on the characteristics of the industry and the actuality of the Association, establish a platform for cooperation among industries, universities and research institutes, launch activities to promote the development of the industry, contribute wisdom and strength to the development of the industry, and promote the results of high-quality development of the industry to verify the effectiveness of Party building, thereby realizing the synchronous resonance of the Party building work with the development of the operation of PhIRDA and mutual reinforcement.

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

maceutical innovation industry

Currently, the global economic pattern is being reshaped with the innovation landscape being reconfigured. Therefore, PhIRDA will continue to focus on systematic research and activities in key areas, analyze the blockages and institutional barriers restricting the development of the innovation cycle at various stages, propose targeted recommendations, continue to advance the in-depth integration of the innovation chain, the industrial chain, the capital chain and the talent chain, and promote the continuous optimization and improvement of the policies of the innovation industry and the market policies.

First, attach importance to the progress of the national implementation program on the whole chain support for the development of innovative drugs, focusing on the major core development areas, concentrating on the weak links, and consolidating the strategic position of the biopharmaceutical industry in the national economy. Targeting the original innovation of medicine and capacity building of clinical research, PhIRDA will undertake the related topics of clinical research driven innovation and development of the pharmaceutical industry by related authorities in Beijing, etc., and promote the synergistic development of the whole innovation chain of the industry.

Second, launch the "Research on the Development Mechanism of Commercial Health Insurance in the Context of Greater Health". PhIRDA will, through an in-depth analysis of the current institutional obstacles to the development of commercial health insurance, explore the establishment of a multi-level medical insurance system that is compatible with the basic medical insurance system and adapted to the national conditions of China, complement the shortcomings of commercial health insurance, reinforce the accessibility and affordability of innovative medicines, and provide strong guarantee and support for the realization of the objective of the "Healthy China Initiative".

Third, establish the "Research Program on Innovative Drug Reimbursement and Access Systems" to explore new approaches for payment of innovative drugs and promote the complementarity between social and commercial healthcare insurance. The focus will be on optimizing medical insurance payment policies—particularly the management, access, and reimbursement mechanisms for drugs listed in the innovative drug directory. This initiative aims to guide the insurance industry to deeply involved with the multi-tiered healthcare security system and to strike a balance between improving medical security and promoting pharmaceutical innovation.

Fourth, set up the project of "Research on Market Access Mechanism of Innovative Drugs and Medical Devices in China", with a view to identify bottlenecks and obstacles in the access process of the pharmaceutical and medical device industries through in-depth analysis of national policy documents, market access rules, industrial development trends, medical insurance reimbursement policies, pricing of pharmaceuticals and medical services, etc., and propose policies for balancing the protection of administrative Policies with the satisfaction of clinical applications, thereby laying a more comprehensive and solid institutional foundation for the development of the new quality productive forces of the pharmaceutical and medical device industries.

Fifth, launch the project of "Research on Opportunities and Challenges of Innovative Pharmaceuticals Going Global in the Middle East", with a view to exploring the market potential of the Middle East region in depth, perform a comparative study on the current situation of cases of going global, analyze the current challenges, and propose strategies for Chinese pharmaceutical and equipment enterprises to expore the international market; meanwhile, promoting the international cooperation between the regulatory authorities and the industry, expediting the upgrading of the industry, and continuously strengthening the international competitive capability.

Six, focus on cutting-edge highlighted areas, launching the "Artificial Intelligence Plus" Initiative in drug R&D, analyzing the current status of application and regulatory difficulties in the field through in-depth understanding of the application scenarios of AI technology in the creation and manufacture of new drugs, with a view to providing specific recommendations related to the cultivation and introduction of comprehensive talents, the establishment of regulatory laws and regulations, the protection of data and information, and the formulation of review guidelines, etc., thereby promoting the wide application of AI technology in the pharmaceutical field and consequently enhancing the innovation and competitive capabilities of the industry.

III. Continuously monitor the participation of market players in the revision of major legislative regimes, policy formulation and implementation process

PhIRDA will continuously monitor the legislative process of the *Law on Healthcare Security of the People's Republic of China* and the *Medical Device Administration Law of the People's Republic of China,* continuously follow the trend of major law revisions such as the Price Law (Revised), the Insurance Law (Revised), and the Social Insurance Law (Revised),

convene thematic symposiums in a timely manner to solicit the recommendations of the industry, and convey the concerns of the industry to the related government authorities with a view to promoting the improvement of the legislation. Furthermore, it will continue to follow up on the revision of the *Regulations for the Implementation of the Drug Administration Law* and the *Regulations for the Protection of Varieties of Traditional Chinese Medicines,* as well as the formulation and revision of the supporting rules and regulations, and proactively solicit suggestions from members and professional committees on the key documents, formulate industry opinions and feed back to the related authorities.

IV. Based on the new development pattern of domestic and international dual circulation and mutual promotion, creating international competitive advantages, and further enhancing China's discourse power 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 in countries along the Belt and Road.

First, PhIRDA plans to organize a high-level delegation of pharmaceutical enterprises to visit related countries in ASEAN/Europe, investigate the local pharmaceutical industry investment environment, and conduct seminars with the medicine and health regulatory authorities, pharmaceutical industry associations, large-scale local medical manufacturing and circulation enterprises, 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 Belt and Road.

Second, PhIRDA will further deepen its cooperation with strategic partners such as Japan Pharmaceutical Manufacturers Association (JPMA) and Korea Pharmaceutical and Bio-Pharma Manufacturers Association (KPBMA) to establish a platform for cooperation and exchange between the pharmaceutical industry and the investment community in China and South Korea, to promote the development of the pharmaceutical innovation industry in Asia, to create an important regional platform for the cooperation among China, Japan, and South Korea in the pharmaceutical industry, and to consolidate the important position of Asia in the field of global pharmaceutical innovation.

(II) Continuously recommend national 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 regulatory authorities 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 international development of pharmaceutical innovation industry in China; 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, assist members in acquiring more R&D trends of new drugs and overseas cooperation opportunities in the pharmaceutical and health field, and promote the deep integration of China's pharmaceutical industry with the international community in trade, investment and technology industries.

V. 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 related organizations at home and abroad to organize the branded events, including the annual China BioMed Innovation and Investment Conference and the Interdisciplinary Oncolytic Virotherapy Innovation Convention, and, based on the branches, fully leverage their professional characteristics to launch various business exchanges, including the China Innovation Conference on Diabetes, Metabolic Diseases and Medical Devices R&D, and the China Pharmaceutical Innovation Policy Forum, with a rich variety of themes, focusing on the key links of pharmaceutical innovation.

VI. Continuously optimize the organizational structure of the branches, pooling high-end resources and elements, promoting the establishment and renewal of branches in an orderly manner, exploring new ideas, opening new paths and providing new methods for promoting cross-border exchanges and innovative development of the medical device industry

In 2025, PhIRDA will further improve the organizational structure of its branches covering the whole chain of expert

resources in the health industry, and consistently adhere to the principles of relying on the resources of the whole chain, adopting an international vision as the unifying principle, being oriented to clinical demands, and addressing the actual demands of the industry, exploring a new mode of differentiated development of its branches, and focusing on a number of cutting-edge core areas in the life and health sector, with a view to building an open cooperation platform for resource sharing, information exchange, mutual benefit and win-win cooperation for all subjects in the whole chain of the big health industry, and contributing to the continuous promotion of high-quality and innovative development of the big health industry in China. According to the overall work plans of branches, in 2025, PhIRDA will newly establish the Specialty Committee on Cell and Gene Therapy, which will co-organize a number of business activities and related working meetings with other specialty committees to comprehensively promote the innovative, sustainable and high-quality development of the healthcare industry.

(I) Make overall planning for the development direction of branches, consolidating resources and elements, precisely focusing on the core demands of the industry, and laying a solid foundation for the sustainable development of branches.

In 2025, the specialty committees on Drug R&D, Medicinal Policy, Pharmaceutical Innovation Investment, Innovative R&D Services, International Regulatory Science, Digital Medicine and Innovative Therapy, Clinical Trial Research, Clinical Research on Cardiovascular Drugs, Clinical Research on Oncology Drugs, Clinical Research on Cranial Nerve, and Innovative Medical Devices will consolidate the resources according to the actual circumstances of the industry, make dynamic adjustments to the direction of operations and complete the work associated with the renewal and re-election. The PhIRDA Clinical Research on Diabetes and Metabolic Diseases Drugs Specialty Committee proposes to extend its term of office until 2026.

(II) Fully leverage the agglomeration advantages of high-end resources and providing professional pharmaceutical and medical device industry information and services for all sector of society.

In 2025, PhIRDA Specialty Committees on Clinical Research on Oncology Drugs and Digital Medicine and Innovative Therapy will conduct research and interview with top institutions and experts, and joint hands with international authoritative media and consulting agencies to timely release the *2024 Review of Clinical Research on New Anti-tumor Drugs in China and the Investigation Report on Artificial Intelligence and the Drug Discovery Industry* for the pharmaceutical and medical device industry as reference for research and investment activities in medical device industry in China.

(III) Continuously promote the implementation of projects such as clinical research and post-marketing clinical trial services for drugs with urgent clinical demands, the formulation and revision of compliance and ethics guidelines for enterprises, as well as the standardization of biobank construction.

VII. Fully leverage the role of think tanks, and deepening pragmatic cooperation with local governments and related institutions based on the advantages of high-end industrial resources

PhIRDA will continue to explore cooperation with local governments (industrial parks), assist local governments at all levels in attracting professional attention in the field of healthcare, introduce a large number of high-end innovative resources in the pharmaceutical and medical device industry, stimulate the clustering effect of high-quality innovative entities in the field of medical devices, facilitate the establishment of a number of national-level innovation transformation platforms and incubators, attract a group of highly educated professionals and investors to establish businesses, cultivate a number of internationally leading innovative enterprises and brands, and continue to contribute to the development of a modern medical and healthcare industry cluster for China!

The report of the 20th National Congress of the Communist Party of China has clarified the overall goals and major tasks to be achieved by 2035 in the field of scientific and technological innovation, and has made special arrangements to accelerate the implementation of the innovation-driven development strategy. Furthermore, it has adhered to the four orientations (adhering to the world’ s scientific and technological frontier, the main battlefield of the economy, major national demands, and the life and health of the people) to accelerate the realization of high-level scientific and technological self-reliance. At the Third Plenary Session of the 20th Central Committee of the Communist Party of China, it has been proposed once again to improve the mechanism for supporting the development of innovative drugs and medical devices, which reflects the determination and firm will of the state to support the development of the pharmaceutical innovation industry.

As an important industry in scientific and technological innovation industry, biopahrmaceutical has a profound impact on the well-being of the public. The year 2025 marks the closing

year and critical stage of the 14th Five-Year Plan, as well as a crucial period for laying the foundation for the 15th Five-Year Plan. In the new year, PhIRDA will further intensify its communication with government authorities, propose recommendations for improving policies and regulations related to innovative drugs and medical devices; proactively establish a platform for collaboration between industry, academia, research institutes and hospitals, promote in-depth cooperation between universities, research institutes, enterprises and capital, expedite the transformation of scientific and technological achievements, and enable the optimal allocation and efficient utilization of innovative resources. Furthermore, it will strengthen exchanges and cooperation with international pharmaceutical organizations, enterprises and research institutes, proactively participate in the development of international rules, enhance China's voice and influence in the global pharmaceutical industry, and create favorable conditions for Chinese pharmaceutical products to go global. In 2025, PhIRDA, as a bridge and connecting link, will continue to join hands with members to seize opportunities, overcome challenges, and make even greater contributions to the high-quality development and innovative upgrading of biopharmaceutical industry in China, to the improvement of well-being and health of the public, and to the construction of a Healthy China.

药促会官网
Official Website of PhIRDA

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