药促会官方微信

WeChat Official Account of PhIRDA

创投大会微信服务号

WeChat Official Account of the CBIIC

会长寄语

继往开来，不负使命

近年来，伴随着医药监管体制改革和更加开放包容的资本市场制度的建立，我国鼓励医药创新的政策环境不断完善，医药产业取得了跨越式的发展。2008年重大新药创制专项设立，吸引了大批海归科学家回国创业，为我国自主医药创新发掘了源动力；2015年药品审评审批制度改革启动，以《国务院关于改革药品医疗器械审评审批制度的意见》、中共中央办公厅和国务院办公厅《关于深化审评审批制度改革鼓励药品医疗器械创新的意见》及新《药品管理法》为纲领的一系列鼓励医药创新、强化知识产权保护的改革措施相继出台，为创新药研发和转化提供了新的加速度；2018年和2019年香港交易所和上海证券交易所允许尚未盈利的生物科技公司上市融资，为以科学家和企业为首的各创新主体在核心技术研发等关键环节提供了强有力的资本支持。

我们欣喜地看到，在几代医药人和社会各界的不懈努力下，我国医药产业正在逐步由简单的数量型增长向高质量型发展转化。中国药促会会员单位在国际医药创新方面实现了重大突破。2018年12月，由珐博进公司研制的"全球新"原研药罗沙司他在中国率先批准上市，标志着我国药品审评审批能力上了新台阶；2019年11月，国家药品监督管理局有条件批准由中国科学院上海药物研究所研发的治疗阿尔茨海默氏症的原创新药甘露糖钠上市，有可能填补在该领域的全球空白；同月，由百济神州自主研发的抗癌新药泽布替尼在美国获批上市；上述成果的实现意味着我国医药创新产业已经从全球医药创新的"跟跑者"转化为"并跑者"并向"领跑者"目标努力！

纵观当前国际形势，我们正处于百年未有之大变局，单边和贸易保护主义愈演愈烈，人才和技术交流合作受阻，资本市场陷入低谷，致使我国医药创新产业面临前所未有的挑战。然而，残酷的竞争也使我们清醒地认识到唯有坚定不移地坚持对外开放，以创新为引领，以合作促共赢，营造开放包容、与时俱进的医药创新政策环境才能让我国医药创新具备不竭活力、走向未来。

中国医药创新促进会作为一家以"创新、产业化、国际化"为宗旨，临床需求为导向，"政产学研用资"紧密结合的全国性社会组织，一直将推动中国医药创新发展作为自身肩负的使命。近年来，中国药促会通过创办中国医药创新与投资大会和医药创新评选活动等一系列标志性品牌活动的方式，搭建国内外交流合作平台，弘扬我国医药创新成果，且在为国家有关部门提供政策建议，参与国家有关法律法规制定以及推动创新成果转化等方面发挥着不可替代的作用。新时代赋予我们新的使命，我愿与各位药促会人一起在已有工作基础上，重点关注医药创新的痛点和难点，不断发掘新的价值，为推动我国医药产业创新和可持续发展，让更多由中国创造的创新药惠及全球患者而不懈努力！

宋晓霖

Message from Chairman of PhIRDA

Futher advance our cause and fulfill our mission

In recent years, with the reform of the pharmaceutical regulatory system and an increasingly open and inclusive capital market system, China is making efforts to improve the policy environment for encouraging pharmaceutical innovation, and China's pharmaceutical industry has developed in leaps and bounds. In 2008, the National Science and Technology Major Project for 'Major New Drug R&D' was established, attracting a large number of scientists back to China to initiated their own businesses and gaining momentum for the independent pharmaceutical innovation in China. In 2015, the reform of the drug review and approval system was launched, releasing a series policies to encourage medical and pharmaceutical innovation and enhance the protection for intellectual property rights, including Opinions on Reforming the Review & Approval System for Drugs and Medical Devices issued by the State Council, Opinion on Deepening the Reform of Review & Approval System to Encourage Innovation in Drug and Medical Devises issued by General Office of the CPC Central Committee and General Office of the State Council, and the new Drug Administration Law, which speeded up the pace of R&D and transformation of innovative drugs; in 2018 and 2019, Hong Kong Exchanges and Clearing Limited (HKEX) and Shanghai Stock Exchange (SSE) launched new listing rules for pre-revenue biotech companies, which provided strong financial support for the technology development and other key links in innovation led by scientists and enterprises.

We feel gratified by the progress that China's pharmaceutical industry is changing its way from simply quantity-based to quality-based development under the tireless efforts from medical and pharmaceutical communities, as well as all walks of life. PhIRDA members has made major breakthroughs in global pharmaceutical innovation. In December 2018, Roxadustat, FibroGen's globally first-in-class drug, received its first approval in China, marking a higher level of China's drug review and approval; in November 2019, GV-971, China's new Alzheimer's drug developed by Shanghai Institute of Materia Medica of CAS, got a conditional approval by National Medical Products Administration (NMPA), which may fill the global gap in this field; same month, Zanubrutinib (BGB-3111), a new anti-cancer drug independently developed by Beigene, was approved for listing in the United States; all above indicates China's pharmaceutical innovation industry changing from a follower to a competitor, and now for the goal of a leader!

Under the current international circumstance, we are facing a period of major change unseen in a century, the growing unilateral and trade protectionism, the blocks on talents and technology exchange and the glooming capital market have presented a huge challenge onto China's pharmaceutical innovation industry. However, it is the cruel competition that bring us a clear fact: we should firmly uphold opening up, take innovation as the guide, carry on win-win cooperation, and create a new policy environment for pharmaceutical innovation, so as to bring China's pharmaceutical Innovation sustained vitality for brighter future.

China Pharmaceutical Innovation and Research Development Association (PhIRDA) is a national-level non-government organization, taking "innovation, industrialization and internationalization" as its principle and clinical needs as its orientation, integrating 'policy, industry, university, research, practice and capital' closely together. PhIRDA always commits itself to promoting the development of China's pharmaceutical innovation. In recent years, through a series of brand activities, including China BioMed Innovation and Investment Conference (CBIIC) and "Dushu Lake Prize" Selection Activities of China Pharmaceutical Innovation Brand, PhIRDA has established a platform for global exchanges and cooperation, and publicizing achievements of China's pharmaceutical innovation. Besides, PhIRDA plays a vital role in providing policy suggestions for national departments and authorities, participating national laws and regulations formulating and promoting transformation of innovation achievements. The new era has given us a new mission. Standing on our history and experience, I would like to work with all members of PhIRDA, focusing on the bottleneck and difficulties in pharmaceutical innovation, keeping discovering new values, and sparing all efforts to promote the innovation and sustainable development of China's pharmaceutical industry, and to let more innovative drugs developed by China benefit the global patients!

Song Rufa

Contents 目录

中国医药创新促进会

中国医药创新促进会，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社会团体组织。

中国医药创新促进会（简称"中国药促会"），原名"中国医药工业科研开发促进会"，2014年10月23日经国家民政部批准更名。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"紧密结合，促进医药行业创新发展。目前，中国药促会有会员单位136家，主要由六个方面成员构成：一是，专注于药品自主创新的在国内医药创新领域处于领先地位的医药企业；二是，专注于医药创新研发的初创型研发企业；三是，专注于医药创新研发服务的机构；四是，从事医药创新研发的国内一流高等院校和科研院所；五是，在新药临床研究领域具有较高水平的临床医疗机构；六是，致力于医药创新投资的金融、投资机构。中国药促会目前成立了药物研发、药物临床研究、医药政策、医药创新投资和创新研发服务专业委员会，即将成立医药企业合规、心血管药物临床研究、脑神经药物临床研究和抗肿瘤药物临床研究等专业委员会，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、投资以及资本市场的全链条组织构架，并作为国际药品制造商协会联合会（IFPMA）的成员继续拓展国际交流渠道。

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

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

Brief Introduction of PhIRDA

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

Formerly named China Pharmaceutical Industry Research and Development Association, the association was approved to rename into PhIRDA by the Ministry of Civil Affairs on October 23, 2014. PhIRDA will exert great effort on "academia-industry collaboration", which centers on the principle of "innovation, industrialization, internationalization", persists in innovation to achieve unmet clinical requirements. At current stage, PhIRDA has 136 members, mainly consisting of six major categories: first, top leading pharmaceutical enterprises focusing on innovation of pharmaceutical products in China, second, start-up and R&D enterprises focusing on innovation of pharmaceutical products; third, institutions focusing on pharmaceutical innovation research and development services; fourth, domestic first-class universities, colleges and research institutions conducting pharmaceutical research and development; fifth, clinical institutions featuring high skills in applicable research on new drugs; sixth, financial and investment institutions committing to pharmaceutical innovation. Moreover, PhIRDA has established the following Specialty Committees: Drug R&D, Clinical Research, Medicinal Policy, Pharmaceutical Innovation Investment and Innovation R&D Services, Ethics and Business Compliance, Clinical Research on Cardiovascular Drugs, Clinical Research on Cranial Nerve Drugs, Clinical Research on Oncology Drugs etc., in order to form 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.

中国医药创新促进会章程

第一章 总则

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

本会会员分布和活动地域为全国。

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

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

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

本会的登记管理机关是民政部，业务主管单位是国务院国有资产监督管理委员会。

本会接受登记管理机关、业务主管单位、有关行业管理部门的业务指导和监督管理。

第四条 本会负责人包括会长、副会长、秘书长。

第五条 本会的住所设在北京市。

本会的网址：www.phirda.com。

第二章 业务范围

第六条 本会的业务范围：

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

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

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

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

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

业务范围中属于法律法规规章规定须经批准的事项，依法经批准后开展。

第三章 会员

第七条 本会的会员为单位会员。

第八条 拥护本会章程，符合下列条件的，可以自愿申请加入本会：

（一）有加入本会的意愿；

（二）在本会的业务领域内具有一定的影响；

（三）本会要求的其他条件。

第九条 会员入会的程序是：

（一）提交入会申请表（盖章）；

（二）提交其他相关材料，包括：

1、单位中文简介（盖章）；

2、单位英文简介（盖章）；

3、本会要求提供的其他材料。

（三）由理事会讨论通过；

（四）由本会颁发会员证，并予以公告。

第十条 会员享有下列权利：

（一）选举权、被选举权和表决权；

（二）对本会工作的知情权、建议权和监督权；

（三）参加本会活动并获得本会服务的优先权；

（四）按规定获得本会发出的信息资料和刊物权；

（五）对本会提出保护合法权益不受侵害的权利；

（六）退会自由。

第十一条 会员履行下列义务：

（一）遵守本会的章程和各项规定；

（二）执行本会的决议；

（三）按规定交纳会费；

（四）维护本会的合法权益；

（五）向本会反映情况，提供有关资料；

（六）完成本会交办的工作。

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

（一）警告；

（二）通报批评；

（三）暂停行使会员权利；

（四）除名。

第十三条 会员退会须书面通知本会并交回会员证。

第十四条 会员有下列情形之一的，自动丧失会员资格：

（一）1年不按规定交纳会费；

（二）1年不按要求参加本会活动；

（三）不再符合会员条件。

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

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

第四章 组织机构

第一节 会员大会

第十七条 会员大会是本会的最高权力机构，其职权是：

（一）制定和修改章程；

（二）决定本会的工作目标和发展规划；

（三）制定和修改理事、监事和负责人产生办法，报业务主管单位备案；

（四）选举和罢免理事、监事；

（五）制定和修改会费标准；

（六）审议理事会的工作报告和财务报告；

（七）决定名誉职务的设立；

（八）审议监事的工作报告；

（九）决定名称变更事宜；

（十）决定终止事宜；

（十一）决定其他重大事宜。

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

会员大会应当采用现场表决方式。

第十九条 经理事会或者本会50%以上的会员提议，应当召开临时会员大会。

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

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

（一）制定和修改章程，决定本会终止，须经到会会员2/3以上表决通过；

（二）选举理事，当选理事得票数不得低于到会会员的1/2；

（三）罢免理事，须经到会会员1/2以上投票通过；

（四）制定或修改会费标准，须经到会会员1/2以上无记名投票方式表决；

（五）其他决议，须经到会会员1/2以上表决通过。

第二节 理事会

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

理事人数最多不得超过48人，不能来自同一会员单位。

本会理事应当符合以下条件：

（一）拥护本会的章程；

（二）有担任本会理事的意愿，支持本会工作；

（三）在本会所从事的领域具有一定影响力。

第二十二条 理事的选举和罢免：

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

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

理事会不能召集的，由1/5以上理事、监事、本会党组织或党建联络员向业务主管单位申请，由业务主管单位组织成立换届工作领导小组（或专门选举委员会），负责换届选举工作；

换届工作领导小组拟定换届方案，应在会员大会召开前2个月报业务主管单位审核；

经业务主管单位同意，召开会员大会，选举和罢免理事；

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

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

第二十四条 理事的权利：

（一）理事会的选举权、被选举权和表决权；

（二）对本会工作情况、财务情况、重大事项的知情权、建议权和监督权；

（三）参与制定内部管理制度，提出意见建议；

（四）向会长或理事会提出召开临时会议的建议权。

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

（一）出席理事会会议，执行理事会决议；

（二）在职责范围内行使权利，不越权；

（三）不利用理事职权谋取不正当利益；

（四）不从事损害本会合法利益的活动；

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

（六）谨慎、认真、勤勉、独立行使被合法赋予的职权；

（七）接受监事对其履行职责的合法监督和合理建议。

第二十六条 理事会的职权是：

（一）执行会员大会的决议；

（二）选举和罢免负责人；

（三）决定名誉职务人选；

（四）筹备召开会员大会，负责换届选举工作；

（五）向会员大会报告工作和财务状况；

（六）决定设立、变更和终止分支机构、代表机构、办事机构和其他所属机构；

（七）决定副秘书长、各所属机构主要负责人的人选；

（八）领导本会各所属机构开展工作；

（九）审议年度工作报告和工作计划；

（十）审议年度财务预算、决算；

（十一）制定分支机构管理办法等重要的管理制度；

（十二）决定本会负责人和工作人员的考核及薪酬管理办法；

（十三）决定其他重大事项。

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

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

理事两次不出席理事会会议，自动丧失理事资格。

第二十九条　负责人由理事会采取无记名投票方式从理事中选举产生。

罢免负责人，须经到会理事2/3以上投票通过。

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

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

第三十二条　经会长或者1/5的理事提议，应当召开临时理事会会议。

会长不能主持临时理事会会议，由提议召集人推举本会一名负责人主持会议。

第三节　会长会议

第三十三条　本会设立会长会议，由本会负责人组成。

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

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

第三十五条　会长会议行使以下职权：

（一）贯彻会员大会和理事会决议；

（二）监督本会各项规章制度以及年度工作计划和年度预算的实施；

（三）向理事会提出建议议题。

第四节　负责人

第三十六条 本会负责人包括会长1名，副会长10-14名，秘书长1名。

本会实行年度轮值会长制度；会长从理事中经选举产生，任期1年。

本会负责人应当具备下列条件：

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

（二）遵纪守法，勤勉尽职，个人社会信用记录良好；

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

（四）身体健康，能正常履责，年龄不超过70周岁，秘书长为专职；

（五）具有完全民事行为能力；

（六）能够忠实、勤勉履行职责，维护本会和会员的合法权益；

（七）无法律法规、国家政策规定不得担任的其他情形。

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

第三十七条 本会负责人任期与理事会相同，连任不超过2届。

第三十八条 会长为本会法定代表人。

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

法定代表人代表本会签署有关重要文件。

本会法定代表人不兼任其他社团的法定代表人。

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

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

第四十条 会长履行下列职责：

（一）召集和主持理事会和会长会议；

（二）检查会员大会、理事会的落实情况；

（三）向会员大会、理事会报告工作。

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

第四十一条 副会长、秘书长协助会长开展工作。秘书长行使下列职责：

（一）协调各机构开展工作；

（二）主持办事机构开展日常工作；

（三）提名副秘书长及所属机构主要负责人，交理事会决定；

（四）决定专职工作人员的聘用；

（五）拟订年度工作报告和工作计划，报理事会审议；

（六）拟订年度财务预算、决算报告，报理事会审议；

（七）拟订内部管理制度，报理事会批准；

（八）处理其他日常事务。

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

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

第五节　监事

第四十三条　本会设监事1-6名。监事任期与理事任期相同，期满可以连任。

本会接受并支持委派监事的监督指导。

第四十四条　监事的选举和罢免：

（一）由会员大会选举产生；

（二）监事的罢免依照其产生程序。

第四十五条　本会的负责人、理事和本会的财务管理人员不得兼任监事。

第四十六条　监事行使下列职权：

（一）列席理事会、会长会议，并对决议事项提出质询或建议；

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

（三）检查本会的财务报告，向会员大会报告监事工作和提出提案；

（四）对负责人、理事、财务管理人员损害本会利益的行为，要求其及时予以纠正；

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

（六）决定其他应由监事审议的事项。

第四十七条　监事应当遵守有关法律法规和本会章程，忠实、勤勉履行职责。

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

第六节　分支机构、代表机构

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

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

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

第五十一条　本会的分支机构、代表机构名称不以各类法人组织的名称命名，不在名称中冠以“中国”、“中华”、“全国”、“国家”等字样，并以“分会”、“专业委员会”、“工作委员会”、“专项基金管理委员会”、“代表处”、“办事处”等字样结束。

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

第五十三条 分支机构、代表机构的财务必须纳入本会法定账户统一管理。

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

第七节 内部管理制度和矛盾解决机制

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

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

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

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

第五章 资产管理、使用原则

第五十九条 本会收入来源：

（一）会费；

（二）捐赠；

（三）政府资助；

（四）在核准的业务范围内开展活动、提供服务的收入；

（五）利息；

（六）其他合法收入。

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

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

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

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

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

第六十五条 本会重大资产配置、处置须经过会员大会或者理事会审议。

第六十六条 理事会决议违反法律、法规或章程规定，致使社会团体遭受损失的，参与审议的理事应当承担责任。但经证明在表决时反对并记载于会议记录的，该理事可免除责任。

第六十七条 本会换届或者更换法定代表人之前必须进行财务审计。

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

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

第六章 信息公开与信用承诺

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

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

第七十条 本会建立年度报告制度，年度报告内容及时向社会公开，接受公众监督。

第七十一条 本会重点围绕服务内容、服务方式、服务对象和收费标准等建立信用承诺制度，并向社会公开信用承诺内容。

第七章 章程的修改程序

第七十二条 对本会章程的修改，由理事会表决通过，提交会员大会审议。

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

第八章 终止程序及终止后的财产处理

第七十四条 本会终止动议由理事会提出，报会员大会表决通过。

第七十五条 本会终止前，应当依法成立清算组织，清理债权债务，处理善后事宜。清算期间，不开展清算以外的活动。

第七十六条 本会经登记管理机关办理注销登记手续后即为终止。

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

第九章 附则

第七十八条 本章程经2019年9月20日第十一届会员大会表决通过。

第七十九条 本章程的解释权属本会的理事会。

第八十条 本章程自登记管理机关核准之日起生效。

Constitution of PhIRDA

Chapter I: General Principle

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

Article 2. The objectives of the Association: Upholding the banner of socialism with Chinese characteristics, taking Deng Xiaoping Theory, the Theory of Three Represents, the Scientific Outlook on Development and Xi Jinping thought on socialism with Chinese characteristics in a new era as our guide, PhIRDA will fully and faithfully apply relevant policies and the reform spirit of the government in our work, improve the scientific research and innovation capacity of China's pharmaceutical industry, promote the transformation of pharmaceutical R&D and innovation achievements, enhance the international competitiveness of China's pharmaceutical industry, protect the legitimate rights and interests of members, build a bridge to communication among the government and industry, and make due contributions to pharmaceutical innovation and social and economic development.
PhIRDA follows the China's related constitution, laws, regulations and policies, practices core socialist values, observes social ethics, consciously promotes credibility building and raises awareness of self-discipline.

Article 3. PhIRDA upholds the unity Party leadership and sets up the Party organizations in accordance with the provisions of the Party Constitution to carry out Party activities and provide necessary service.
PhIRDA was registered in the Ministry of Civil Affairs of the People's Republic of China, and administrated by State-owned Assets Supervision and Administration Commission of the State Board of Directors.
PhIRDA receives administration by the registration authority, the administrative department and the relevant industry administrative departments.

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

Article 5. The residence of PhIRDA is in Beijing.
The website of the PhIRDA: www.phirda.com.

Chapter II: Business Range

Article 6. Business range of PhIRDA:
(1) To carry out and implement relevant policies on Chinese pharmaceutical industry development made by the Central Committee of CPC and the State Council, perform in-depth research on new drug development and Chinese pharmaceutical innovation system, scientifically forecast the direction of new drug development, timely propose the suggestions for development of Chinese pharmaceutical industry, reflect members' reasonable suggestions and demands, and assist members to solve practical problems.
(2) To organize and participate in the events for exchanging and communication, promote China's pharmaceutical industry development. To organize and participate in the relevant academic exchanges, promote the pharmaceutical industry combination of scientific research and practices, advance the relevant research cooperation and academic-achieve transformation, and assist to industrialization and specification of

the high technology.
(3) To fully play PhIRDA's advantages and modern technologies in collecting, studying and releasing information on pharmaceutical science and technology, focus on the key issues of industry and provide consulting service.
(4) To promote the international communication of China's pharmaceutical industry, and organize diverse cooperation and exchanges on information, technologies and personnel.
(5) To implement National Innovation-driven Development Strategy, build a platform for cooperation in pharmaceutical innovation, and promote social capital into innovative drug R&D projects.
The matters within the business range requires approval and prescribed by laws, regulations and rules shall be carried out upon approval according to law.

Chapter III: Members

Article 7. PhIRDA Members: Institutional members.

Article 8. Applicant members who uphold the constitution of the Association and meet the following conditions may voluntarily apply to join the Association:
(1) Be willing to join the Association;
(2) Possess certain influences in the PhIRDA's business range;
(3) Meet other conditions required by the Association.

Article 9. Procedures of joining the Association:
(1) Submitting application (with stamp);
(2) Submitting other relevant materials, including:
1. Introduction in Chinese (with stamp);
2. Introduction in English (with stamp);
3. Other materials required by the Association.
(3) Being approved through discussion by the Board of Directors;
(4) Membership will be issued by the Association and announced.

Article 10. Rights and duties of members:
(1) The rights of election, being elected and vote;
(2) The rights to be informed, advise and supervise the work of the Association;
(3) The rights to participate in the Association activities and obtain services from Association;
(4) The rights to have access to information and publications issued by the Association;
(5) The right on protection of legitimate rights and interests;
(6) The freedom of quitting the Association.

Article 11. Duties of the members:
(1) Obey the Constitution and regulations of PhIRDA;
(2) Implement the decision of the Association;
(3) Pay membership dues on time as per the stipulation;
(4) Protect the legal rights and interests of the Association;
(5) Provide information requested by the Association;
(6) Complete the work entrusted by the Association.

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

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

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

Article 14. The member will automatically lose its membership under any of the following circumstances:
(1) Refuse to pay membership dues on time as per the stipulation for 1 year;
(2) Refuse to participate the activities of the Association as per the stipulation for 1 year;
(3) No longer meet the membership conditions.

Article 15. After withdrawing from the Association, automatically losing the membership or being removed with membership, the position, rights and obligations of the member in the Association will be terminated automatically.

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

Chapter IV: Organization Structure

Section One: PhIRDA General Assembly

Article 17. The PhIRDA General Assembly is the highest powerful organization of the Association. Functions of the PhIRDA General Assembly include:
(1) Composing and revising the Constitution of the Association;
(2) Deciding on the objectives and development plan of the Association;
(3) Formulating and revising the method of electing Directors, Supervisors and persons in charge, and reporting to the administrative department as record;
(4) Electing and recalling Directors and Supervisors;
(5) Establishing and modifying the membership fee standard;
(6) Reviewing working report and financial report of the Board of Directors;
(7) Deciding the establishment of honorary position;
(8) Reviewing working report of Supervisors;
(9) Deciding the name change of the Association;
(10) Deciding termination of the Association;
(11) Deciding other important issues.

Article 18. The PhIRDA General Assembly shall be held at least once every five years. PhIRDA members shall be notified of the issue of General Assembly15 days in advance.
The PhIRDA General Assembly shall adopt the form of on-site voting.

Article 19. An Interim General Assembly shall be held upon the proposal of the Board of Directors or the members of the Association of more than 50%.
The Interim General Assembly shall be chaired by the Chairman. If Chairman is not be able to chair, a charge person proposed by the Board of Directors or members shall be elected.

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

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

Section Two: Board of Directors

Article 21. The Board of Directors is the executive body of the PhIRDA General Assembly. During the period when the PhIRDA General Assembly is not in session, the Board of Directors shall carry out work and be responsible for the PhIRDA General Assembly.
The maximum number of Directors shall not exceed 48, and they shall not come from the same member unit.
The Directors of the Association shall meet the following requirements:
(1) Upholding the Constitution of the Association;
(2) Be willing to act as the Director of the Association and support the work of the Association;
(3) Possessing certain influences in the business range of the Association.

Article 22. Election and recall of Directors
(1) The first session of Directors shall be jointly nominated by the members upon the application of the sponsor and submitted to the administrative department for approval, and then elected by the PhIRDA General Assembly;
(2) For the term change of the Board of Directors, the Board of Directors shall nominate a leading group (or special election committee) consisting of the representatives of the Directors, the Supervisors, the Party organizations and PhIRDA members six months prior to the convening of the PhIRDA General Assembly;
If the Board of Directors is unable to be convened, more than 1/5 of the Directors, Supervisors, Party organizations or Party building liaison officers shall apply to the administrative department, and organize a leading group (or special election committee) to be responsible for the election of the new term;
The leading group for term change shall draft a term change plan, which shall be reported to the administrative department for review and approval 2 months prior to the holding of the PhIRDA General Assembly;
With the consent of the administrative department, the PhIRDA General Assembly shall be held to elect and recall the Directors;
(3) With the authorization of the PhIRDA General Assembly, the Board of Directors may add and recall some of the Directors in the session, no more than 1/5 of the total number of the original Directors.

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

Article 24. Rights of Directors:
(1) The rights of election, being elected and vote;
(2) The rights to know, advise and supervise the work, financial situation and major matters of the Association;
(3) The rights to participate in the development of internal management system and provide comments and suggestions;
(4) The rights to propose to the Chairman or the Board of Directors to hold an interim meeting.

Article 25. The Directors shall abide by the laws, regulations and the Constitution of the Association, faithfully perform their duties, safeguard the interests of the Association and perform the following obligations:

(1) To attend meetings of the Board of Directors and implement the resolutions of the Board of Directors;
(2) To exercise rights within the scope of their duties and powers

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

Article 26. Functions of the Board of Directors:
(1) Implementing the decisions by PhIRDA General Assembly;
(2) Electing and recalling the persons in charge;
(3) Nominating honorary position;
(4) Preparing for the holding of the PhIRDA General Assembly and taking charge of election at expiration of office terms;
(5) Reporting work and financial situations to the PhIRDA General Assembly;
(6) Making decision on the establishment, modification and termination of branches, representative offices, offices and other subordinate bodies;
(7) Nominating the deputy secretary-general and the principal responsible persons of all subordinate institutions;
(8) Leading the work of the institutions affiliated to the Association;
(9) Deliberating annual work reports and work plans;
(10) Deliberating annual financial budget and final settlement;
(11) Formulating management measures for branch offices and other important management systems;
(12) Deciding on the measures for the assessment and salary management of the person in charge and staff of the Association;
(13) Deciding other important issues.

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

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

Article 29. The person in charge shall be elected by the Board of Directors through secret ballot from the Directors.
The recall of the person in charge shall be approved by more than 2/3 of the Directors present.

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

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

Article 32. An interim Board of Directors meeting shall be convened upon the proposal of the Chairman or 1/5 of the Directors.
The Chairman shall not preside over the interim Board of Directors meeting, and the convener shall elect a person in charge from the Association to preside over the meeting.

Section Three: Chairman Meeting

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

Article 34. The Chairman Meeting shall be convened upon the decision of the Chairman with over 2/3 of the persons in charge, and theresolution shall come into effect only when passed by over 2/3 of the persons in charge.
An interim Chairman Meeting shall be convened upon the proposal of the Chairman or 1/3 of the persons in charge.

Article 35. Functions of the Chairman Meeting:
(1) Implementing the decisions of the PhIRDA General Assembly and the Board of Directors;
(2) Supervising the implementation of the rules and regulations of the Association as well as the annual work plan and annual budget;
(3) Proposing topics to the Board of Directors.

Section Four: Association Leaders

Article 36. The leaders of the Association include one Chairman, 10-14 Vice Presidents and one Secretary-General.
The Association applies system of annual Chairman rotation; the Chairman shall be elected from members, and the term is 1 year.
The leaders of the Association must meet the following requirements:
(1) Adhering to the Party leadership, upholding socialism with Chinese characteristics, resolutely implementing political direction, guidelines and policies, and possessing good political qualities;
(2) Complying with laws and disciplines, working with due diligence, and possessing good social credibility;
(3) Mastering professional knowledge, experience and ability, being familiar with the industry situation, and possessing great influence in the business field of the Association;
(4) Being in good health, able to perform normal duties, and aged no more than 70 years old, and the Secretary-General should be in full-time position;
(5) With ability of complete civil behavior;
(6) Being able to perform duties faithfully and diligently, and protect the legitimate rights and interests of the Association and its members;
(7) There is no other circumstance that laws, regulations and national policies prohibiting the holding of the post.
The Chairman and the Secretary-General shall not concurrently hold the counterpart in other social organizations. The Chairman and the Secretary-General shall not be concurrently held by the same person and shall not come from the same member unit.

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

Article 38. The Chairman is the legal person of the Association.
Under special circumstances, upon the agreement of the Chairman and the Board of Directors, and upon the review and approval of the administrative department and the approval of the registration authority, the Vice President or the Secretary-General may act as the legal person. The Secretary-General employed or publicly recruited shall not be the legal person of the Association. The legal person will represent PhIRDA to sign the relevant documents.
The legal person is not allowed to hold a counterpart position in other associations.

Article 39. After the person in charge who serves as the legal person is recalled or leaves office, he/she will no longer perform the functions and powers of the legal person of the Association. Within 20 days after being recalled or retiring from office, the Association shall apply to the registration authority for registration of change after reporting to the administrative department for review and approval.
Where the former legal person fails to cooperate in the modification registration of the legal person, the Association may, according to the resolution of the Board of Directors on approving the modification, report to the administrative department for review and approval, and then apply to the registration authority for registration modification.

Article 40. Function and powers executed by the Chairman:

(1) Calling for and hosting the PhIRDA General Assembly;

(2) Examining the implementation of decisions made by the PhIRDA General Assembly;
(3) Report work to the PhIRDA General Assembly and the Board of Directors.
The Chairman shall report annually to the Board of Directors. A Vice President elected by the Board of Directors or appointed by the Chairman who cannot fulfill his or her duty.

Article 41. The Vice President and the Secretary-General shall assist the Chairman in carrying out the work, the functions executed by the Secretary-General include:
(1) To coordinate the work of various administrative sectors;
(2) To be in charge and organize administrative sectors to do routine work;
(3) To nominate the Deputy Secretary-General and representatives of sub-branches for the PhIRDA General Assembly's approval.
(4) To manage the employment of full-time working staffs for the Association;
(5) To draft the annual work report and work plan, and submit them to the Board of Directors for deliberation;
(6) To prepare the annual financial budget and final settlement report, and submit them to the Board of Directors for deliberation;
(7) To draw up the internal management system and submit it to the Board of Directors for approval;
(8) In charge of executing other routine affairs.

Article 42. Meeting summary shall be made for the PhIRDA General Assembly and Board of Directors meeting. Where a decision is made, a written report shall be made and verified and signed by the members present at the meeting. The Meeting summary and decisions of the meeting shall be circulated to the members or kept for future reference in an appropriate manner for at least 10 years.
The election result of Directors or persons in charge shall be reported to the administrative department for review and approval within 20 days, and upon approval, be reported to the registration authority for archival filing and to the members for notification or future reference.

Section Five: Supervisors

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

Article 44. The election and recall of a supervisor:
(1) The Supervisors are elected by the PhIRDA General Assembly;
(2) The recall of Supervisors shall be subject to the procedures for their election.

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

Article 46. The functions executed by the Supervisors include:
(1) To attend the Board of Directors Meeting and Chairman Meeting, and make queries or suggestions on matters to be resolved;
(2) To supervise the performance of the duties of the Association by the Directors and persons in charge, and put forward suggestions for the recall of the personnel who seriously violates the Constitution of the Association or the resolutions of the PhIRDA General Assembly;
(3) To examine the financial report of the Association, report the work of Supervisors and present proposals to the PhIRDA General Assembly;
(4) To rectify any acts damage the interests of the Association of the persons in charge, Directors or financial managers in a timely manner;
(5) To report the problems existing in the work of the Association to the administrative department, industry administrative department, registration authority and competent taxation and accounting departments;
(6) To decide on other matters to be deliberated by the Supervisors.

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

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

Section Six: Branch and Representative Office

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

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

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

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

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

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

Section Seven: Internal management system and conflict resolution mechanism

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

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

Article 57. If the certificate or stamp of the Association is lost, upon the approval of 2/3 or more of the Directors of the Board of Directors, and the loss statement is published in a publicly released newspaper or periodical, an application may be filed with the registration authority for re-development or engraving. If they are illegally embezzled by an individual, it shall be required to return through legal means.

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

Chapter V: Assets Management and Utilization

Article 59. Source of revenue of the Association:
(1) Member annual fee;
(2) Donation;
(3) Government subsidies;
(4) Income from activities and service approved business range;
(5) Interests;
(6) Other income from legitimate sources.

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

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

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

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

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

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

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

Article 67. Prior to any replacement or the expiration of the legal person of the Association, he/she must be subjected to the financial audit. During the term of the legal person, the legal person shall bear the relevant liabilities for the violation of the *Regulation on Registration and Administration of Social Organizations* and the Constitution of Association. Where any illegal act or property loss of a social organization is caused due to the legal person's dereliction of duty, the legal person shall bear individual liabilities.

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

Chapter VI: Information Disclosure and Credit Commitment

Article 69. In accordance with the relevant policies and regulations, the Association shall perform the obligation of information disclosure, establish an information disclosure system, timely provide members with annual work reports, reports issued by third-party institutions,

income and expenditure of membership fees, and other information that should be released considered by the Board of Directors, and timely release the information to the public including registered items, Constitution of Association, organizational institutions, donations accepted, credibility, commitments, items transferred or entrusted by the government, services provided, and the state quo.
The Association shall establish a spokesperson system. The spokesperson, appointed or designated by the Board of Directors will respond to social concerns in the form of regular or irregular press conferences, briefings, interviews, etc. on major events or hot issues of the Association. The contents of news release shall be examined and approved by the legal representative or the chief person in charge of the Association, so as to ensure the correct guidance of public opinions.

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

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

Chapter VII: Revision Procedure of the Constitution

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

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

Chapter VIII: Termination Procedure and Post-dissolution Assets management

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

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

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

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

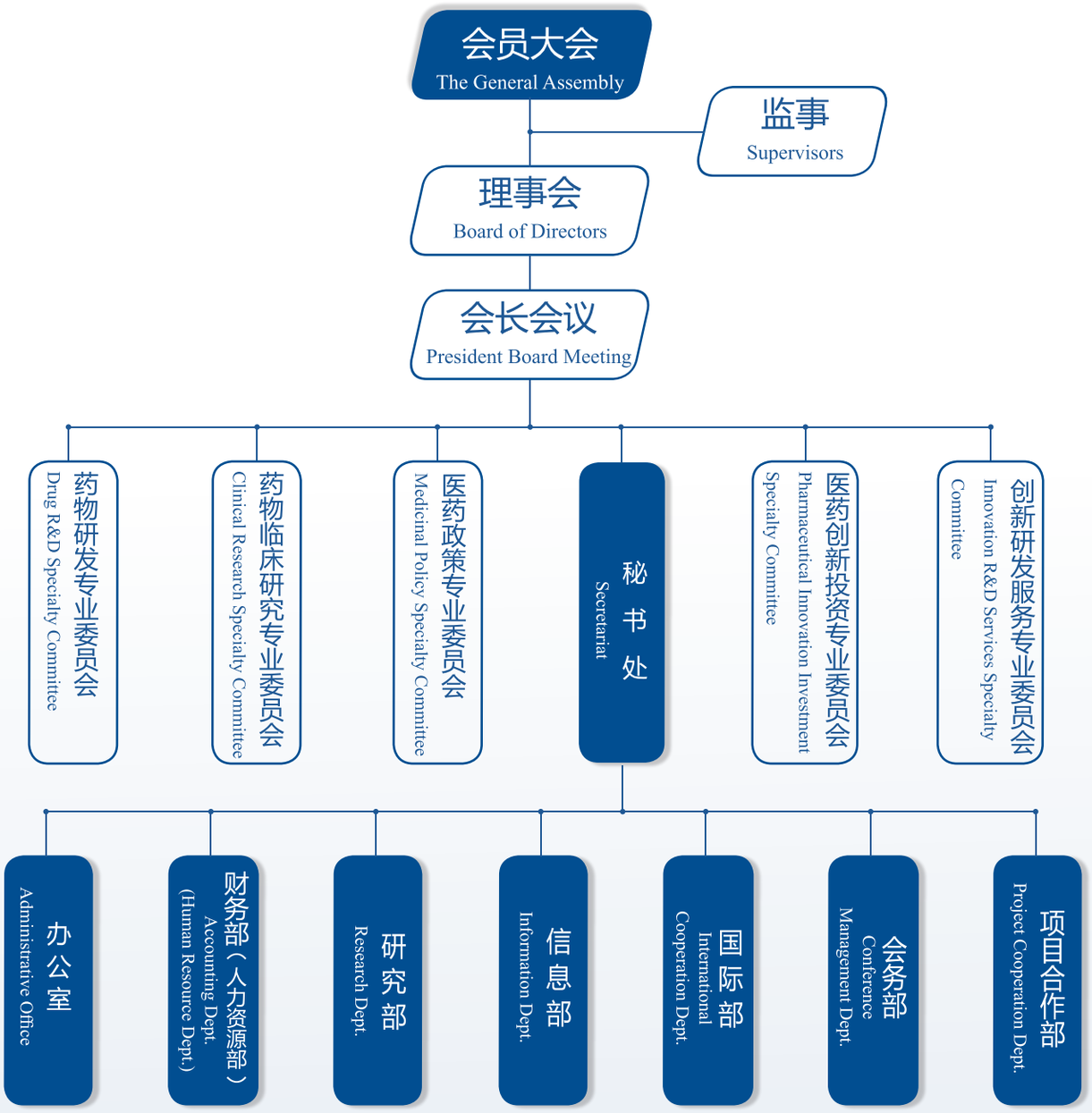
Chapter IX: Appendix

Article 78. This Constitution was approved by the 11th PhIRDA General Assembly on September 20th, 2019.

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

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

机构设置
Organization Structure of Association



会领导介绍 | Introduction of PhIRDA Leadership

第九届会员大会以来历任会长照片

Chairman of PhIRDA Since the 9th General Assembly

桑国卫

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

Sang Guowei

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

陈启宇

2012-2013年度会长
上海复星医药（集团）股份有限公司
执行董事、董事长

Chen Qiyu

Annual Chairman 2012-2013
Executive Director, Chairman of the Board, Shanghai Fosun Pharmaceutical (Group) Co., Ltd.

闫希军

2013-2014年度会长
天士力控股集团董事局主席

Yan Xijun

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

孙飘扬

2014-2015年度会长
江苏恒瑞医药股份有限公司董事长

Sun Piaoyang

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

蒋华良

2015-2016年度会长
中国科学院院士
中国科学院上海药物研究所学术委员会主任、研究员

Jiang Hualiang

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

丁列明

2016-2017年度会长
贝达药业股份有限公司董事长兼CEO

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

蒋建东

2017-2018年度会长
中国医学科学院药物研究所所长

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

刘殿波

2018-2019年度会长
绿叶制药集团有限公司董事长

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

宋瑞霖

2019-2020年度会长
中国医药创新促进会

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

现任会领导
Current Leadership of PhIRDA

会长　宋瑞霖

中国医药创新促进会

Song Ruilin, Chairman
China Pharmaceutical Innovation and Research Development Association

副会长　任晋生

先声药业有限公司董事长

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

副会长　陈启宇

上海复星医药（集团）股份有限公司执行董事、董事长

Chen Qiyu, Vice President
Executive Director, Chairman of the Board, Shanghai Fosun Pharmaceutical (Group) Co., Ltd.

副会长　孙飘扬

江苏恒瑞医药股份有限公司董事长

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

副会长　丁列明

贝达药业股份有限公司董事长兼CEO

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

副会长　蒋建东

中国医学科学院药物研究所所长

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

副会长　刘殿波

绿叶制药集团有限公司董事长

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

副会长　柯尊洪

成都康弘药业集团股份有限公司董事长

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

副会长　李 佳

中国科学院上海药物研究所所长

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

副会长　闫凯境

天士力医药集团股份有限公司董事长

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

副会长　赵 勇

上海医药集团股份有限公司党委副书记、副总裁

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

副会长　张抒扬

北京协和医院党委书记、副院长

Zhang Shuyang, Vice President
Secretary of the Party & Vice President, Peking Union Medical College Hospital

副会长　李 燕

山东齐鲁制药集团有限公司总裁

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

副会长　吴晓滨

百济神州中国区总经理兼总裁

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

秘书长　冯 岚

中国医药创新促进会

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

中国医药创新促进会第十届 (2014-2019) 工作总结暨第十一届 (2019-2024) 工作建议

——2019年9月20日第十一届会员大会

执行会长 宋瑞霖

各位会员（代表）：

受会长会议的委托，我向第十一届会员大会报告中国医药创新促进会（以下称"我会"）第十届（2014-2019）重点工作，并对我会第十一届（2019-2024）重点工作提出建议，请各位代表审议。

第一部分 第十届（2014-2019）重点工作回顾

自2014年我会第十届会员大会第一次会议以来，我会全面贯彻落实党的十八大、十九大精神，坚持改革创新，紧跟时代步伐，将"创新、产业化、国际化"的办会宗旨贯穿工作始终。在历任会长领导和会员单位等共同努力下，完成了重塑创新内核的结构性转变，形成了以医药创新研发机构为主，聚合主流医药创新投资机构的贯穿医药产业全链条的平台型协会组织。

为了顺应国家全面深化体制改革和推动产业向高质量发展的要求，我会主动开展关键政策制度研究，共完成政府委托或购买服务5项，参与国家有关法律法规起草制定9次，向有关部门提出建议26项，提供研究课题咨询服务12次，制定行业标准10项，向政府反映行业及会员诉求16项，为营造良好创新政策环境做出了不懈努力。为应对国际形势日益严峻的挑战，我会积极扩展医药创新国际交流与合作，并通过参与人用药品注册技术国际协调会（ICH）指南制修订及在我国的转化实施，为会员单位快速提升综合竞争和创新能力搭建高层平台，目前涉及国际合作项目31项；借助香港交易所上市规则改革与粤港澳大湾区建设所带来的机遇，我会搭建了促进医药创新与投资融合的多级平台，为推动医药产业创新发展贡献力量。目前，我会已成为行业监管部门认可、在医药创新界具有重大影响力的医药社团组织。

五年来我会重点围绕在以下七个方面开展工作。

一、全面落实新时代党组织建设总体要求

根据党中央加强社会主义党建工作要求，我会于2016年12月建立了中国工经联第十党支部，在中国工经联党委的领导下，积极开展组织学习，通过严格党的组织生活、强化党员管理教育、做好党员组织关系管理、及时发展党员等工作，不断加强党员管理，发挥党员先锋示范作用，团结群众，从社会组织工作层面推动党的事业全面发展。根据党中央要求，大力开展"不忘初心、牢记使命"主题教育活动，深入学习总书记重要讲话及相关精神，并努力与我会实际工作紧密结合。

二、不断完善内部治理结构和组织机构建设

（一）调整组织机构，完善法人治理结构

1、完善法人治理结构。随着会员单位数量不断扩大，我会现行组织机构和管理制度已经不能适应我会发展需求。依照社团管理相关规定，建议恢复理事会议事制度，设立由会员大会、理事会领导，秘书处为常设办事机构的组织架构。

2、加强制度、法治建设。完善了《会员及会费管理办法》、《信息及新闻公开办法》、《会员大会选举规程》、《理事会选举规程》及分支机构财务和管理办法等规范性文件，规范我会财务、固定资产、考勤、印章、行文、证书、安全、课题研究等

活动，使我会各项工作步入规范化管理轨道。

3、推进信用体系建设。我会在中国社会组织网、“信用中国”网站和我会官网，主动进行关键信息公示，接受会员单位、新闻媒体和社会公众的监督。

4、健全行业自律。我会制定了《中国医药创新促进会医药企业伦理准则》，引导会员合法合规竞争，营造诚信执业良好氛围。

（二）设立专业分支机构，强化医药创新服务关键环节

根据第十届会员大会相关决议，我会发起成立了“药物研发”、“药物临床研究”、“医药政策”、“医药创新投资”和“创新研发服务”5个专业委员会，并制定了《中国医药创新促进会专业委员会管理办法》、《中国医药创新促进会专业委员会财务管理制度》和中国医药创新促进会投资专委会、创新研发服务专委会工作办法。各专业委员会成立后积极推进各项工作，成绩斐然。

1、中国医药创新促进会药物研发专业委员会

中国医药创新促进会药物研发专业委员会（以下称“研发专委会”）自2015年4月21日成立以来，秉承搭建医药产业领域合作交流的平台、推动我国医药产业创新发展的主旨，深入研究构建中国医药创新体系相关问题，积极参与医药领域重大政策的研讨，提出了系列鼓励医药产业创新的政策建议，为推动药品审评审批监管政策与国际接轨发挥了重要作用。

2、中国医药创新促进会药物临床研究专业委员会

中国医药创新促进会药物临床研究专业委员会（以下称“临床专委会”）自2015年4月21日成立以来，以“提高中国创新药物研发水平与临床研究水平，推动我国医药产业创新、健康发展”为重要目标，充分发挥临床专家资源优势，协助我会深度参与“国际创新临床研究大会”（以下称“GCP大会”）、“中国医药药学政策论坛”（以下称“药学论坛”）、“‘独墅湖杯’医药创新品牌评选活动”（以下称“品牌评选活动”）等多项专业活动的筹备，积极推荐专家进入ICH指南相关工作小组参与指南修订工作，并配合我会完成对“重大新药创制”科技重大专项实施成果的第三方评估工作。

3、中国医药创新促进会医药政策专业委员会

中国医药创新促进会医药政策专业委员会（以下称“政策专委会”）自2015年7月3日成立以来，密切关注热点政策话题，在各委员专家的同心协力下，整合多方研究资源，围绕药品招标采购、临床试验数据核查、药师在医保控费及医院用药管理中的作用、药品上市许可持有人制度、医保支付标准、“全球新”概念下中国创新药物医保准入机制等主题开展了课题、研讨会、论坛等形式多样的研究活动，并在活动中达成权威共识，为我会会员单位乃至整个医药行业的具体政策诉求积极呼吁，为我会构建更完善的医药创新政策环境相关工作贡献力量。

4、中国医药创新促进会医药创新投资专业委员会

投资专委会成立于2016年3月29日，旨在践行国家创新驱动发展和资本服务实体经济的战略指导精神，共享并合理配置医药产业投资资源，为拓宽我国医药创新产业投融资渠道、搭建国际化的资本合作平台，推动社会资本加大对医药创新的支持力度，使资本成为创新成果转化的催化剂，营造更加科学、更富吸引力的医药创新投资环境，为我国乃至全球医药产业的创新发展做出积极贡献。投资专委会自成立以来，紧紧围绕“医药创新和资本高效对接”的工作宗旨，充分发挥投资人的资源优势，创办了中国生物医药创新投资人论坛，协助我会筹划投资大会投资人经验分享论坛、跨境并购论坛、科创板主题论坛和上市服务机构专场，并深度参与香港交易所及科创板上市制度改革等多项重大活动。

5、中国医药创新促进会创新研发服务专业委员会

创新研发服务专委会成立于2017年11月29日，包含合同研究组织（CRO）和合同开发与生产组织（CDMO），旨在通过为会员单位及国内外企业提供高标准、全方位的医药创新研发服务，形成具有国际竞争力的新药研发核心服务商集群，助力创新成果的转化。创新研发服务专委会自成立以来协助我会筹划投资大会创新研发服务专场，解读中国医药研发外包服务行业现状，为创新药与重磅药开发提供更高效快捷的服务。

（三）加强秘书处自身建设

为更好服务会员单位，我会秘书处新设会务部和项目合作部。今年我会还开展了社会组织评估工作，评估组专家对我会各方面工作给予高度评价。我会按照国家规定开展的行业协会脱钩工作也在稳妥推进中。

三、努力营造医药创新良好政策环境

（一）发挥行业智库作用，为完善医药政策建言献策

1、深化药品审评审批等监管体制改革建议

（1）对药品监管体制改革及《药品管理法》等法律法规修订提出意见

①推动药品审评审批与药品知识产权保护制度改革

2016年，我会向原国家食品药品监督管理总局（CFDA）提交在我国实施知识产权保护制度改革可行性及完善临床试验管理报告中建议：将临床试验机构管理从认证制改为备案制，设立区域性伦理委员会，将伦理委员会的伦理审查前置至IND申报前，对企业参与的国际多中心临床试验结果予以认可；强化中国数据保护制度，允许改良型新药提交新药申请时使用文献及公开的非申请人研究所得数据；建立中国的橘皮书制度和专利链接制度，专利纠纷由司法诉讼解决，对挑战专利成功的首仿药给予一定期限的市场独占期。

我会负责人作为唯一受邀行业专家代表，参加2017年5月19日国务院汪洋副总理在中南海主持召开的药品知识产权保护制度改革国务院部门协调会议并发表意见建议，受到高度关注，为促进中央认可在我国探索药品专利链接制度，试行专利期补偿制度提供了专业意见。本次国务院部门协调会议为2017年10月8日中共中央办公厅、国务院办公厅公布的《关于深化审评审批制度改革鼓励药品医疗器械创新的意见》（厅字〔2017〕42号，以下简称"42号文"）奠定基础。我会上述报告中的8条建议也被42号文采纳。

②提出符合国情的药品知识产权制度建议

受CFDA委托，我会撰写了《药品管理法》相关知识产权条款修订建议稿及修订说明，提出在我国建立药品专利链接制度、完善数据保护制度和给予挑战专利成功仿制药市场独占期的相关建议；提出在我国建立药品专利链接制度及开展专利期补偿试点等工作实施建议方案。这些研究成果为在我国探索专利链接制度和实行专利期延长制度发挥了积极作用。

③对药品管理法修订草案提出意见

我会对《药品管理法（修订草案）》（以下称"药品管理法"）多次提出修改意见。2019年5月6日，全国人大常委会法制工作委员会行政法室负责人到访我会就第十三届全国人大常委会审议的药品管理法听取我会及创新会员单位意见。我会提出的"允许各地建立区域和中心伦理委员会以提高伦理审查效率"、"鼓励罕见病用药和儿童用药研发"等多项建议被全国人大常委会审议通过的《药品管理法》所采纳。

④提出完善药品审评收费制度建议报告，助力药品注册收费法制化

针对部分企业向"国务院减轻企业负担部际联席会议"督察组反映药品注册收费加重企业负担，建议取消或停征收费的问题，我会受国家药品监督管理局（NMPA）委托，组织会员单位和专家开展研讨，并结合我会对国际药品注册收费制度的系统研究，形成了包括通过立法明确药品注册收费专用于提高审评效率、定期开展审评费用使用绩效评估、合并补充申请收费以减轻企业负担等完善注册收费制度的建议报告。该报告受到药监局主要领导同志的高度重视，专门批复相关司室正式回函提出补充意见。报告正式报送发改委和财政部等有关部门后受到两部门认可。

（2）提出完善药品审评审批法规建议

①提出化学药品新注册分类建议方案

2015年5月22日我会主动提出化学药品注册分类改革方案获得CFDA认可，其后多次受注册司委托，对化学药品新注册分类细化及技术要求提出建议。分类改革建议在2015年8月18日国务院发布的《关于改革药品医疗器械审评审批制度的意见》（国发〔2015〕44号）中得到体现，为药品按类科学审评提供基础。

②对临床试验数据核查提出建议

2015年12月，CFDA召开"临床试验数据自查核查工作如何有序开展"交流工作会，为全面开展临床数据国家核查征求产业与临床机构意见。会后，我会起草报送CFDA《关于有序推进临床试验数据核查工作和规范开展临床试验的建议》中提出，建立GCP规范下的临床试验运行机制，放开临床试验机构前置资质审查，建立以风险控制为核心的国家地方分工监管体系。我会基于公正维护行业健康发展的意见，获得了医药界的一致好评和CFDA有关领导的高度重视。国家临床数据核查开展以来，有效推动了我国药品研发生态的重建。

③就取消新药监测期、完善药品试验数据保护制度提出建议

受NMPA委托，针对《药品注册管理办法》修订是否取消新药监测期开展研究，提出取消新药监测期、落实完善我国药品试验数据保护制度等建议。

④对药品注册管理办法及其配套技术规定等提出建议

受NMPA委托，参与对《药品注册管理办法》初稿中"临床试验"和"上市许可"两部分的修订，组织会员单位和专家对《药品注册管理办法》相关技术需重新修订的文件进行梳理并提出建议修订文件目录，以推动《药品注册管理办法》及配套文件的同步修订。

对《药品注册现场检查管理规定（征求意见稿）》、《已上市化学仿制药（注射剂）一致性评价申报资料要求（征求意见稿）》提出意见建议，参与《注册分类3类化药临床技术要求》起草。

⑤为促进我国生物制品创新发展提出建议

受NMPA委托，我会围绕改革生物制品注册分类、优化审批流程、鼓励生物类似药开发、技术审评与生产现场检查同步及工艺验证批次产品上市销售等形成建议报告。我会应邀出席NMPA举办的"中国生物制品创新发展座谈会"，就推动药品监管规范化、科学化、效率化做了发言。焦红局长针对我会意见，批示CDE并召集有关司处就相关法规修订进行研究。

（3）对其他药品监管相关法律法规修订提出建议

受全国人大教科文卫委员会邀请，我会参加了《中华人民共和国疫苗管理法（征求意见稿）》（以下简称"疫苗管理法"）征求意见座谈会，针对厘清疫苗管理法与药品管理法法律关系、优化疫苗临床试验审评、扩大生物制品批签发检验机构范围、解决疫苗储存和配送温控等疫苗监管关键问题提出了建设性意见。

我会还针对第十三届全国人大常委会第七次会议审议的《中华人民共和国专利法修正案（草案）》，给全国人大常委会法制工作委员会撰写报告，建议对在我国申请注册的所有创新药（并非必须在中国境内与境外同步申请上市）给予专利期限补偿以推动中国本土创新，得到积极回应。

2、完善我国医疗保障体制与药品准入机制建议

（1）为建立中国特色医疗保障体制提出建议

我会在2016年1月26日人社部组织召开的"医药卫生体制改革专题讲座"和2018年8月15日医保局组织召开的"全面建立中国特色医疗保障制度专题研究"座谈会上，介绍推动医疗、医保、医药"三医联动"的建议，提出建立更加主动的医保药品支付制度，以循证医学为基础、药物经济学评估为手段，对目录药品调整进行综合评审等，受到人社部和医保局领导同志的高度关注。

（2）对2017版、2019版医保药品目录调整工作提出建议，我会负责人作为咨询专家参与医保药品目录调整工作，积极推动将符合条件的新药和高质仿制药纳入备选名单，发挥了行业协会的重要作用。

（3）对完善医保目录动态调整机制、医保谈判原则提出建议

受原人社部医保司委托，我会针对医保谈判原则等问题提出：应当以药品的综合价值及性价比作为主要评估依据，采取多元化、多类别谈判策略；国家谈判品种省级不应当开展二次谈判，在谈判有效期内谈判品种直接挂网采购。我会大部分建议在实际开展的医保药品谈判工作中被采纳。

（4）对国家药品集中采购试点工作方案提出意见建议

针对高价抗癌药及已有通过仿制药质量一致性评价品种的国家药品集中采购试点工作方案（以下简称"集采试点"），围绕试点原则、品种范围、招标供货与落实采购量方式及医保支付标准制定等提出意见。

针对4+7集中采购政策，中国科学院与中国工程院部分院士牵头与我会共同撰写了完善集采试点建议报告，报送中央全面深化改革委员会及习近平总书记。报告提出当前我国医药产业处于结构转型调整期，企业创新药研发投入主要来源于仿制药销售利润，建议国家集采摈弃唯低价、唯一中标模式，并将流通环节节省成本适当反哺通过一致性评价的优秀品种，以激发企业创新与提高仿制药质量的积极性。在近期第二轮国家药品集采方案中，唯一中标规则已更改为在认可最低价基础上允许最多3家企业品种中标（暂定）。

我会还围绕创新药准入医保、获得合理支付价格，实现成果转化、惠及患者等行业热点问题，积极开展课题研究，为医保部门建立创新药的准入机制提供契合国情的解决方案。

3、在全国政协双周座谈会上就提高我国仿制药质量发表见解和建议

我会负责人受邀参加由时任中共中央政治局常委、全国政协主席俞正声主持的第43次全国政协双周协商座谈会，与全国政协委员、专家学者以及国务院有关部委负责人共同就提高我国仿制药质量的问题与对策进行讨论协商，并建议必须完善我国药品招标、使用政策，为优质仿制药建立规范的市场环境，促进临床用药优先使用优质仿制药。全国政协特别将我会意见纳入简报上报中央，并在后续发布的国家相关政策文件中予以采纳。

4、关于完善我国药品采购使用机制的其他建议

（1）针对药品招标采购制度的专项研究建议被国办7号文采纳

2014年底，我会受国家卫计委委托，围绕药品招标采购制度"最低价中标"规定的弊端和危害形成建议报告报送国务院领导和国家卫计委、国务院医改办等部门。《关于完善公立医院药品集中采购工作的指导意见》（以下称"国办7号文"）有关招采合一、量价挂钩、完善双信封制、分类采购的指导思想是我会与医药行业同仁共同呼吁的结果。

（2）为农工党中央撰写完善药品集中采购的建议，获国务院领导批示

2015年4月我会受农工党中央委托撰写的《关于完善我国药品集中采购机制的研究报告》受到农工党中央主席、全国人大常委会副委员长陈竺院士高度认可，并作为农工党中央《关于建立医疗卫生机构核心用药制度及做好药品集中采购工作的建议》的核心内容，上报国务院领导同志。国务院领导批示：请国家卫生计生委、人社部阅研，在药品采购中要充分调动各方力量真正实现招采合一，量价挂钩，切实压缩药价高水分，并在整合和修订医保目录中考虑。

5、评估中美贸易摩擦对我国生物医药产业的影响

2018年11月，受工业和信息化部委托，我会正开展"中美贸易摩擦对医药产业发展影响"的研究，通过评估影响寻找解决对策。调研与阶段性研究结果显示，现阶段中美贸易摩擦对医药人才交流、技术合作、在美开展临床试验和市场开拓、融资等方面均有不同程度的影响。接下来，我会将以此课题为抓手，着力研究应对当前贸易摩擦挑战的发展策略。

（二）坚决维护会员单位和行业合法权益，为医药产业健康发展不断呼吁

1、针对各省卫生部门主导的药品招标采购工作及时提出改正建议

我会先后对湖南、安徽蚌埠、浙江、福建等省市药品招标采购政策存在问题及时进行研究，并正式发文提出建议，得到了

大部分药品招采部门正面回应。针对湖南省药品招标办负责人对我会进行指责并扬言起诉，我会通过在官网公开发布声明，摆事实、讲道理，向湖南省药品招标办重申我会观点和意见。此举在业界和全国药品招标部门引起了较大反响，我会敢于坚持真理、仗义执言的精神赢得了各界的赞赏。另外，我会针对安徽省蚌埠市卫计委在药品采购工作中违背中央鼓励创新、简政放权、让市场在资源配置中发挥决定性作用的精神，甚至涉嫌违反《民法通则》、《合同法》、《反垄断法》等法律的错误做法，依法向国家发展改革委、原国家工商总局举报。国家发改委向安徽省政府办公厅发出《国家发展改革委办公厅关于建议纠正蚌埠市卫生计生委滥用行政权力排除限制竞争有关行为的函》（发改办价监[2015]2175号，以下称"2175号文"），对蚌埠市卫计委药品采购工作错误做法予以否定。这是国家发展改革委依法启动的全国第一例涉及医改的反垄断调查，对全国各地药品采购工作起到了指导、示范作用。

2、对人类遗传资源审批制度导致临床试验滞后提出改进建议

原人类遗传资源审批制度占用大量的临床试验时间，导致在中国开展临床试验显著滞后严重影响我国患者用药可及。我会建议：简化审批环节，一些样品数量少的试验只需要向国务院科学技术行政部门备案。该建议体现在国务院发布的《中华人民共和国人类遗传资源管理条例（国令第717号）》中。

（三）作为独立第三方承担"重大新药创制"科技重大专项"十一五"、"十二五"实施绩效的评估工作

我会受国家卫生计生委委托，作为独立第三方机构，对"重大新药创制"科技重大专项（以下简称"专项"）在"十一五"、"十二五"期间的实施绩效进行评估。我会邀请行业内知名临床、药学、药物经济学专家29人组成专项评估专家委员会，制定了以定量客观数据指标为主、定性主观评价指标为辅的评价指标体系，通过重点项目汇报、实地考察、现场评估，围绕专项实施亮点成果进行提炼总结，并就专项运营管理模式的改进等问题提出许多建设性意见。国家卫计委已将评估报告正式付印。

（四）开展其他课题研究

五年来，我会始终坚持围绕我国医药政策领域热点问题进行自主专题研究，并赴美国、法国、德国和日本进行考察调研，通过研究和借鉴国际先进国家和地区支持医药创新发展的制度设计与经验，为研究完善我国鼓励医药创新相关政策与制度建设奠定基础。我会已结题与在研的课题十余项，涉及药品招标采购、药品审评收费制度、药品价格管理体制改革、仿制药产业发展、创新药医保准入路径、医保支付标准形成机制、知识产权保护相关制度建设等主题。

（五）推动罕见病事业发展

我会与北京协和医院、中国医院协会、中国研究型医院学会等单位共同发起成立了"中国罕见病联盟"（以下简称"联盟"），我会被推举为副理事长单位；参与组织了《中国第一批罕见病目录释义》、《罕见病诊疗指南（2019版）》的发布，以及启动第二批罕见病目录遴选相关工作。

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

（一）创办医药创新品牌评选活动，挖掘最有价值的中国医药创新品种，表彰最具影响力的创新人物

2015年我会发起创立了"中国医药创新最具影响力品牌系列评选活动"，旨在充分贯彻落实党中央、国务院关于创新驱动发展和品牌引领创新的战略。2018年，评选活动转为与苏州工业园区合作，并更名为"'独墅湖杯'医药创新品牌评选"（以下简称"品牌评选"）。品牌评选活动充分借鉴国际科学奖项评选规则，首创以医药创新活动/成果满足重大临床需求、为社会及经济等领域做出突出贡献作为主要评价指标；吸纳了包括两院及外籍院士在内的众多临床、药学知名专家，组成了行业最权威、专业覆盖领域最广的评审专家委员会（56位委员其中17位院士），为评选出我国真正具有创新价值的创新药物和最具创新能力的药物研发及临床研究领军人物（包括华人科学家），提升品牌评选的科学权威性、公正公平性奠定了重要基础。品牌评选是非盈利性公益活动，不收取任何评选费用。迄今，品牌评选已成功举办三届。今年品牌评选已经完成提名奖项评选，有品种与人物等共13个项目入

围。第四届品牌评选活动颁奖典礼定于9月21日晚在苏州广播电视总台演播厅举行。

（二）在Nature发文向世界展示中国医药创新成果，获国务院领导同志肯定，并获评"十大医学科技新闻奖"

我会组织专家撰写"从仿制到创新"系列综述文章在《Nature》杂志刊登，是我国首次在世界舞台系统展示了近十年来中国医药从仿制向创新转型取得的显著成果，在国内外产生非常积极的影响。刘延东副总理特别批示给予肯定。该系列文章在由《健康报社》联合中华医学会、中国医学科学院、国家卫生计生委科技发展中心等单位联合主办的国内外医学科技新闻评选中，被评为"2017年度中国十大医学科技新闻"。

（三）我会负责人多次接受国内外媒体访谈，宣传中国医药创新成果

我会负责人接受《焦点访谈-新药审批进入快车道》专访，介绍近年来中国医药产业发展及药品审评审批体制改革成果。这是医药行业协会首次登上《焦点访谈》，是对我会助推药品监管改革的充分肯定。我会负责人还多次接受包括央视新闻周刊、人民网、Pharmaceutical Executive（《医药经理人》）、腾讯新闻《棱镜》栏目及香港南华早报等国内外权威媒体的采访，对中国医药创新发展及药品监管改革进行宣传推介。

五、营造包容、富有活力的医药创新投资环境

（一）创办中国医药创新与投资大会

我会创办的中国医药创新与投资大会（以下称"大会"）是国内首个具有广泛影响力、权威性的多元化成果转化及国际合作交流平台。三届大会共吸引25个创新品种临床数据全球首发、320余个项目（企业）参与路演、1000余家投资机构和1500余家医药创新企业到会，总参会人数6500余人。

今年第四届大会定于2019年9月21日-23日在苏州工业园区举办。本次大会特邀国家药品监管局有关负责人权威解读新修订的《药品管理法》；邀请全球顶级药物研发科学家和纳斯达克、香港、伦敦和上海四大知名证券交易所重量级嘉宾首次共聚中国，热议全球医药创新及创新融资平台对医药创新领域的融资支持政策及未来发展趋势。本次大会在往届多项活动基础上新增上市服务相关机构、创新研发服务和科创板主题论坛及大数据+智慧医疗、AI+生物医药、国际肿瘤药等多个路演专场，为宣传展示我国医药创新成果，行业政策发展走向，促进研发项目国内外合作、吸引社会资本参与创新搭台。

（二）深度参与香港资本市场创新改革

2018年香港交易及结算所有限公司（以下称"港交所"）对主板《上市规则》进行了改革。在《上市规则》公开征询意见阶段，我会与港交所进行深入交流并签署战略合作协议。我会提出允许尚未盈利生物科技公司赴港上市的建议获采纳，宋瑞霖执行会长、田源博士等5位来自我会专家被聘为香港联交所生物科技咨询小组成员。已赴香港挂牌上市的7家未盈利生物科技公司中有6家为我会会员单位；今年上半年全球十大生物科技IPO中，港交所上市公司占5席，其中有2家为我会会员单位（豪森和基石药业），豪森更位列2019上半年全球十大IPO首位，上市首日市值超千亿港币。港交所上市新政对于提升市场活跃度及在全球生物科技融资平台地位具有重大意义。

此外，我会还将在第四届投资大会期间，与港交所共同召开闭门企业座谈会，围绕香港资本市场的发展持续交流意见。

（三）促进上交所科创板为医药创新融资服务

上海证券交易所（以下称"上交所"）设立科创板，意味着中国医药创新企业除纳斯达克和港交所之外有了新的上市选择。我会会员单位微芯制药成为首个登陆上交所科创板并创下首日最高市盈率等多项新高的创新企业。

第四届投资大会上还设立了科创板主题论坛，以便上交所宣讲科创板新政，为拟赴科创板上市的创新型医药企业提供交流和合作机会。

六、开展医药产业国际交流

（一）积极加入国际组织，为我国创新成果走向国际舞台发挥更积极的作用

我会作为唯一代表中国本土制药企业的成员组织加入国际药品制造商协会联合会（IFPMA）并受邀成为亚洲制药组织合作会议（APAC）成员。助力中国更多参与国际药品监管标准制定，促进医药创新国际交流与合作。

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

1、我会已与美国、英国、荷兰、加拿大等国家驻华使领馆，世界卫生组织、世界贸易组织、世界知识产权组织、国际药品制造商协会联合会（IFPMA）、美国药品研究与制造商协会（PhRMA）、美国全球生物技术工业组织（BIO）、美国癌症研究基金会（NFCR）、欧洲制药工业协会（EFPIA）、日本制药工业协会（JPMA）等40多个机构建立密切联系，合作举办多场活动，加深了会员医药企业对各国监管体系的了解。

2、近五年，我会组团访问美国、德国、荷兰、瑞士、法国、澳大利亚、日本、以色列等各国政府部门、科研院所、医药创新企业和行业协会，深入了解各国鼓励医药创新政策和世界领先创新研究成果，为加强医药产业合作，拓展国际市场提供服务与支持。

3、近五年，我会受邀参加J.P.摩根健康产业大会、亚洲制药组织合作会议（APAC）、金砖国家卫生部长会议、亚太经合组织（APEC）中小企业商业伦理论坛等国际创新、投资、监管类主题国际会议，向世界展现我国医药创新发展情况，学习其它国家和地区先进监管经验。

4、我会先后与消除癌症计划组织（ECI）、美国癌症研究基金会（NFCR）、美国华裔血液及肿瘤专家学会（CAHON）、生物技术工业组织（BIO）、中国外商投资企业协会药品研制和开发行业委员会（RDPAC）、苏州工业园区管委会和首都医科大学附属北京天坛医院等机构合作，主办了“国家国际医药创新合作论坛—金砖国家面临的挑战与机遇”、“中美生物医药创新合作研讨会”和“中美肿瘤专家圆桌会议”等会议，为进一步拓展国际交流与合作发挥积极作用。

（三）积极参与国际规则制定，为政府提供决策建议

受国家药品监管局ICH工作办公室委托，我会多次组织相关指南培训，对53个ICH指南征求会员单位意见。受IFPMA委托，我会已向IFPMA 15个ICH工作组推荐30名专家（包括11名组长，6名候补组长），直接参与到ICH指南制定和实施；为ICH工作办公室下设29个国内专家工作小组推荐了16位专家进入到10个工作小组。

七、不断提高医药信息服务能力

（一）搜集整理医药行业最新动态消息

我会坚持每天搜集、编辑、整理医药行业最新动态编辑《医药信息简报》，向会员单位及业内专家、政府部门、合作机构提供最新医药行业发展及政策动态，并在我会官网发布。

（二）运用微信自媒体便捷沟通，传递信息

开通我会微信公众账号和投资大会服务号，建立微信自媒体平台，广泛宣传我会对医药政策研究意见建议，推送行业热点信息，受到业界广泛关注。截至目前，我会微信公众号和投资大会服务号累计关注人数超过一万人。

各位代表，通过五年的努力，我会取得了一些成果，实现了一些突破，在国内外医药行业的影响力也在逐步提升。所有这一切离不开会员单位的共同努力和社会各界的支持。在此，我谨对长期以来支持我会工作的各部门领导、专家、会员单位表示衷心感谢！

虽然我们取得了一些成绩，但是我们还要清醒地认识到，我会的创新发展还面临许多亟待解决的问题，秘书处的工作能力

和服务水平还有待提高，我会的活动内容和活动方式还需要进一步创新和完善。下一步，我会将在已有工作基础上，认真总结经验，系统研究行业发展痛点与我会未来发展定位，全面提升我会综合服务实力，更好的适应改革发展新形势，努力推动自身与会员单位、产业的共同发展。

第二部分 第十一届（2019-2024）工作建议

过去的五年，中国医药行业发生了天翻地覆的变化，如果说药品审批改革、上市许可持有人制度试点等鼓励创新政策的实施为产业发展开启了加速引擎，那么仿制药一致性评价、药品追溯责任制建立，医保控费和药企财务核查政策传递的是严格规范、向高质量转型的信号。医药创新需要全球合作。面对世界经济全面下行、国际形势动荡变化、单边和贸易保护主义愈演愈烈，资本市场陷入了募资难、投资难的窘境。人才、技术交流合作受阻，让中国医药创新发展面临更多挑战。无论是行业、会员单位还是我会，坚持以创新带动发展，快速实现新旧动能转换都显得尤为重要。

未来我会将瞄准制约医药创新发展的关键性问题，重点研究推进与高质量创新发展相适应的机制体制建设，通过进一步拓展合作领域，与有关政府、行业部门及行业组织建立广泛联系与合作，着力推动医药产业生态环境不断优化，助力市场竞争新优势培育，为促进医药产业持续健康发展贡献力量。具体工作建议如下：

一、进一步加强党组织建设，开创党建工作新局面

党的十九大对社会组织在社会治理、协商民主、基层党组织建设等方面都提出了明确要求，要将社会组织建设成为巩固党的执政基础的重要力量。我会将加强党员理论学习，培养并吸纳优秀骨干加入党组织，强化党对我会业务工作的领导，使党建工作与我会重点工作紧密结合、互促共进。

二、全力配合上级主管单位，保障脱钩改革平稳落地

行业协会商会脱钩改革是在习近平新时代中国特色社会主义思想指导下，党中央国务院作出的重大决策部署。我会将坚定不移地贯彻执行国家发改委、民政部、中央组织部等十部门《关于全面推开行业协会商会与行政机关脱钩改革的实施意见》要求，全力做好"五分离、五规范"，保障平稳、及时、高效地完成脱钩改革任务。

三、踊跃投身脱贫攻坚事业，坚决打赢脱贫攻坚战

参与脱贫攻坚，既是我会的重要责任，又是我会服务国家、服务社会、服务群众、服务行业的重要体现。我会将深入学习贯彻习近平总书记关于扶贫开发的重要战略思想，认真落实党中央、国务院关于脱贫攻坚决策部署，把助力脱贫攻坚和精准救助作为当前和今后一个时期我会的重要任务，同时引导会员单位，发挥资金、技术、市场、管理等优势，从"产业扶贫"、"教育扶贫"、"健康扶贫"和"志愿扶贫"等方面着手，为如期打赢脱贫攻坚战，实现全面建成小康社会目标持续贡献力量。

四、开展重大医药政策研究，积极为政府有关部门建言献策

长远来看，创新研发能力将是行业、企业发展核心竞争力所在，良好的政策环境至关重要。我会将充分借助行业智库专家智慧和资源，围绕影响医药行业创新发展的痛点难点开展专项研究，为政府部门、会员单位及医药行业出谋划策、贡献政策智慧。

（一）认真开展《药品管理法》的宣传贯彻与实施工作，组织力量开展药品管理法实施条例及配套政策研究，向国家有关部门提出建设性建议，保证我国药品监管改革政策顺利推进。

（二）我会将与中国社会科学院蓝迪国际智库合作，研究通过“一带一路”促进国内医药企业产品走出去的策略，为中国药企更快进入国际市场打通路径。

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

（四）与国内医药行业组织或者有关单位建立广泛联系，共同推进医药行业重大主题研究，发表行业发展研究报告或者蓝皮书等，让社会更多了解医药行业，也为改善行业发展环境造势。

五、不断开拓创新，引领会员和医药产业创新发展

（一）深度参与科创板改革试点工作

我会将在现有工作基础上持续关注科创板相关政策，积极配合中国证监会和上交所，组织拟在科创板上市的医药创新企业、行业专家和学者不定期举办座谈会，为科创板平稳运行持续提供建议。

（二）办好品牌标志性活动

不断开拓创新，拓宽服务内涵，做好GCP大会、药学政策论坛、投资大会等品牌标志性活动，使我会的活动更加与时俱进。

（三）发起设立医药创新发展（苏州）基金会

我会正在积极推动医药创新发展（苏州）基金会（以下简称“基金会”）的注册工作，未来将联合基金会一起办好品牌评选活动，并探索扩大基金会在慈善赠药与扶贫和扩展募捐渠道等方面的工作，使之成为助推我国医药产业创新发展的新力量。

（四）把握粤港澳大湾区发展机遇，推动生物医药产业发展

按照中共中央、国务院《粤港澳大湾区发展规划纲要》和中央全面深化改革委员会《关于支持深圳建设中国特色社会主义先行示范区的意见》文件精神，我会与深圳市坪山区人民政府签订合作协议，共同推动中国医药创新、共建粤港澳大湾区生物医药创新高地。未来，我会将与坪山区共同面向全球整合生物产业创新资源，以高端会议、招商推介、创新项目引进等方面全面深化合作，努力为中国医药创新作出积极贡献。

另外，我会还将继续积极参与罕见病联盟相关工作，为推进相关政策环境改善，加速罕见病防治战略体系建设做出努力。

六、继续拓宽国际合作渠道和空间，加强国际交流

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

我会将继续按照IFPMA-ICH秘书处和CDE的需求，推荐相关专业领域的权威专家参与ICH技术指南的制修订工作，积极参与国际标准和规则制定，做好ICH相关指导原则在中国转化实施的培训工作，为推动我国药品研发和风险管理水平与国际接轨，提升我国医药企业创新和国际竞争力贡献力量。

（二）与国内外相关机构建立创新研发协作机制，组织国际交流活动，共同推动我国药物创新水平提高与国际接轨

我会将继续拓展与各国驻华使领馆、政府机构和行业协会之间的产业交流合作，在科研、临床、产业、政策等多方面开展交流与合作，为会员单位寻求海外合作机会，促进我国医药产业在贸易、投资和技术等领域与国际的深入融合，共同搭建国际医药创新交流平台。

七、优化内部治理结构，加强专业委员会和秘书处建设，提升自身综合能力

未来五年，我会将继续优化内部治理结构并加强秘书处建设；改革现有专业委员会设置，成立顾问咨询委员会；增设心血管、肿瘤、脑神经和药学四个领域药物临床研究专业委员会；吸引高素质人才加入，为会员单位和整个医药产业发展提供更加优

质的服务；创新信息服务模式，及时、快捷地为政府、会员单位及业界同仁提供编辑整理的政策及产业最新资讯；系统完善我会各项内部管理制度，加强诚信自律建设，做到公开、透明、规范、民主办会。

各位代表，中国医药行业已经进入了整合转型大变局时代，道阻且长、唯有创新。我会将继续围绕"创新、产业化、国际化"的办会宗旨，不断拓展服务内涵和外延，团结并动员会员单位，做好政府与产业之间的桥梁和纽带，加强行业自律，维护会员合法权益，为推动我国医药产业的创新和可持续发展，保障人民群众健康，实现"两个一百年"奋斗目标、实现中华民族伟大复兴的中国梦不断做出新的贡献！

以上报告，请予审议。

Work Summary of the 10th General Assembly (2014-2019) of PhIRDA and Work Proposal for the 11th General Assembly (2019-2024)

----The 11th General Assembly, September 20, 2019

Song Ruilin, Executive President of PhIRDA

Dear Members (representatives),

With the entrustment by the Chairman Meeting and for the purpose of your deliberation, I hereby deliver a report to all PhIRDA members on the work of 2014 to 2019 of China Pharmaceutical Innovation and Research Development Association (hereinafter referred to as 'PhIRDA') to the 11th General Assembly (2019 to 2024) and propose suggestions on key works of the 11th General Assembly.

Part I Work Summary of the 10th General Assembly (2014-2019)

Since the first meeting of the 10th General Assembly in 2014, PhIRDA has acted in full accordance with the spirit of the 18th and 19th National Congress of the Communist Party of China and adhered to reform and innovation. To keep up with the times, PhIRDA has closely integrated our principle 'Innovation, Industrialization and Internationalization' throughout the work. With the concerted efforts of the successive Chairmen and PhIRDA members, PhIRDA has realized structural transformation of reshaping the core of innovation. Consequently, a platform-based association has come into being. It focuses on pharmaceutical innovation research organizations, gathers mainstream pharmaceutical innovation investors and runs through the entire chain of pharmaceutical industry. To comply with the requirements of the state to comprehensively deepen institutional reform and to realize positive development of the industry, PhIRDA has positively taken the initiative in launching studies on key policies and systems, completed 5 projects entrusted or purchased by government, engaged in drafting relevant national laws and regulations for 9 times, submitted 26 proposals to relevant departments, and delivered consultation service on research topics for 12 times. PhIRDA has also developed 10 industrial standards and reflected 16 industry and member appeals to the government. All the efforts have made a difference in terms of the favorable policy atmosphere for innovation. To address increasingly severe challenges in global setting, PhIRDA would energetically expand relevant international exchange and cooperation. PhIRDA actively takes part in the development and revision of the ICH Guideline and its transformation and implementation in China, with a hope to build a high-caliber platform for the members to enhance overall competitiveness and innovation. For the moment, PhIRDA has been engaged in 31 international cooperation projects. What's more, by seizing the opportunities brought by the listing reform of the Hong Kong Stock Exchange and the construction of Guangdong-Hong Kong-Macao Greater Bay Area, PhIRDA has built multi-level platforms to facilitate the integration of pharmaceutical innovation and investment and to contribute to originality and development in the industry. Now, PhIRDA has been a pharmaceutical organization with significant influence in the field of drug innovation, winning the recognition from regulatory authorities.

In the past five years, PhIRDA's key work focused on the 7 aspects as follows.

I. Comprehensively met the overall requirements for Party construction in the new era

In accordance with the requirements of the Party Central Committee to make further efforts in socialism Party construction, PhIRDA established the 10th Party branch of the China Federation of Industrial Economics (CFIR) in December 2016. Under the Party committee of CFIR's leadership, PhIRDA actively organized study activities. Through a series of tasks such as strict organizational life, management education for Party members, management of organizational relationship, prompt introduction of Party members, PhIRDA has constantly strengthened the management of Party members, given full play to their leading role and rallied support from the public. With social organization, Party's cause has witnessed all-around development. In accordance with the requirements of the Party Central Committee, PhIRDA has vigorously organized educational activities, with the theme as 'Stay True to and Keep in Mind the Mission'. PhIRDA has delved into the General Secretary Xi's key speeches and spirits and attempted to do so based on our actual work.

II. Constantly improved internal governance structure and organizational structure

(I) Adjusted organizational structure and improved legal person governance structure

1. Improved the structure of legal person governance. As more members join the association, the current organizational structure and management system failed to meet development needs. As per relevant regulations on social organization management, it was recommended to resume the Board of Directors. PhIRDA will establish a structure with the leadership by the General Assembly and Board of Directors, in addition to the permanent office, Secretariat.

2. Strengthened system and legal construction. PhIRDA improved normative documents, including the *Measures for the Administration of Members and Membership Fee, Regulations on Information and News Publicity, Election Procedure of PhIRDA General Assembly, Election Procedure of PhIRDA Board of Directors*, as well as financial and management regulations for branch offices. This would help regulate our finance, fixed assets, attendance, seals, documents, certificates, security, research projects, etc., enabling our tasks to be on right track.

3. Promoted credit system construction. PhIRDA willingly disclosed key information on the website of the 'China Social Organization' and 'Credit China', in addition to the official website of PhIRDA. By doing so, it accepted the supervision of PhIRDA members, the media and the public.

4. Improved industry self-discipline. PhIRDA formulated the *Code of Ethics of PhIRDA for Pharmaceutical Enterprises*, so as to guide members to partake in conforming and legal competition and create sound atmosphere on integrity-based operation.

(II) Established Specialty Committees to improve key links in pharmaceutical innovation services

According to the relevant resolutions of the 10 th General Assembly, PhIRDA has set 5 Specialty Committees, including Drug R&D Specialty Committee, Clinical Research Specialty Committee, Medicinal Policy Specialty Committee, Pharmaceutical Innovation Investment Specialty Committee, and Innovation R&D Services Specialty Committee. PhIRDA also formulate the A*dministrative Measures on the Specialty Committees of PhIRDA*, the *Financial Management Regulations for the Specialty Committees of PhIRDA*, as well as the work regulations for the Pharmaceutical Innovation Investment Specialty Committee and the Innovation R&D Services Specialty Committee. After the establishment of the committees, works were actively promoted with reaping fruitful results.

1. Drug R&D Specialty Committee

Since its establishment on April 21, 2015, the Drug R&D Specialty Committee of PhIRDA has adhered to the mission of building cooperation and exchanges platform for pharmaceutical industry. It launched in-depth study on the matters regarding the construction of China's new pharmaceutical innovation system, vigorously discussed major policies in the pharmaceutical field and proposed policy recommendations for encouraging innovation. These efforts played a significant role in advancing regulations on drug review, approval and supervision in accordance with international standards.

2. Clinical Research Specialty Committee

Since its establishment on April 21, 2015, the Clinical Research Specialty Committee of PhIRDA has aimed to improve China's development and clinical study of innovative drugs and facilitate industrial innovation and sound development in the field. For instance, to give full play to the advantages of clinical experts, it assisted PhIRDA in hosting professional activities, including the China Cardiovascular Disease Clinical Research Quality Management Standard (GCP) Conference, China Hospital Pharmacy Policy Forum, and 'Dushu Lake Prize' Selection of China Pharmaceutical Innovation Brand. It actively recommended experts to participate in the relevant ICH work groups for revision of the ICH Guideline and cooperated with us on third-party evaluation on the implementation results of the National Science and Technology Major Project for Major New Drug Research and Development.

3. Medicinal Policy Specialty Committee

Since its establishment on July 3, 2015, the Medicinal Policy Specialty Committee of PhIRDA has kept close eye to hot policies and issues. With the concerted efforts from relevant experts, the committee has integrated multi-party research resources and launched a variety of research activities such as projects, seminars and forums regarding drug bidding and centralized drug procurement, auditing of clinical trial data, the role of pharmacists in controlling insurance expenditure and hospital medication management, marketing authorization holder system, medical insurance payment standards, and Chinese health insurance access system of innovative drugs under the concept of 'First-in-class'. During the activities, it reached an authoritative consensus and actively called for necessary policies for members and experts, contributing to PhIRDA's work on building more comprehensive policy environment for medical innovation.

4. Pharmaceutical Innovation Investment Specialty Committee

The Pharmaceutical Innovation Investment Specialty Committee, established on March 29, 2016, aims to practice national strategic guideline of innovation-driven development and capital-based real economy, share and rationally allocate investment resources in drug industry, and expand the investment and financing channels for China's pharmaceutical innovation. It also attempts to build an international capital cooperation platform and encourage the support by social capitals for pharmaceutical innovation, rendering capital as catalyst for transformation of innovation achievements. In the end, it will create a more scientific and attractive investment environment for pharmaceutical innovation and contribute to innovative development of the industry at home and abroad. Since its inception, it has focused on the purpose of 'Effective Connection between Pharmaceutical Innovation and Capital' and allowed full play to the resource advantages of investors. It established the China BioMed Innovation Investors Forum, and assisted in hosting Investors' Experience Sharing Forum, Cross Border M&A Forum, SSE STAR Market Forum, and Service Agencies Roadshow on CBIIC. Meanwhile, it deeply participated in multiple activities such as listing system reform of the Hong Kong Stock Exchange and the SSE STAR Market.

5. Innovation R&D Services Specialty Committee

The Innovation R&D Services Specialty Committee established on November 29, 2017, consists of CRO and CDMO. It is committed to providing high-quality and comprehensive pharmaceutical innovation and development service for members as well as domestic and foreign companies, forming a globally competitive group of service providers for new drug development and facilitating transformation of innovation achievements. Since its inception, the committee has assisted PhIRDA in planning and hosting the Service Company Roadshow Session on CBIIC, and interpreted the current status of China's outsourcing pharmaceutical development service, so as to deliver more efficient and convenient service for innovative and important drugs.

(III) Strengthened the construction of the Secretariat

To better serve PhIRDA member, the Secretariat set up the Conference Management Department and Project Cooperation Department. This year, PhIRDA also organized evaluation on social organizations. The experts of the evaluation team spoke highly of all aspects of PhIRDA's work. PhIRDA has been steadily advancing the decoupling from the administrative department in accordance with relevant national regulations.

III. Strove for sound policy environment for pharmaceutical innovation

(I) Fully play the role of industrial think tank and propose suggestions for improving pharmaceutical policy

1. Suggestions on deepen reform of drug review and approval regulatory system

(1) Advice on the reform of drug regulatory system and the revision of laws and regulations including the *Drug Administration Law*

① Promote reform of the drug review and approval system and intellectual property protection

In 2016, PhIRDA proposed some advice to the former CFDA in the *Report on the Feasibility of Implementing the Reform of Intellectual Property Protection System and Improving Clinical Trial Management in China*. To change certification system into registration system for the management of clinical trial institutions, establish regional ethics committee, advance ethical review before IND declaration, and accept the results of international multi-center clinical trials joined by enterprises. To strictly implement China's system of data protection and permit the use of the data arising from non-applicant studies in certain literatures or available to the public when it comes to the application for modified new drugs. To establish China orange book and patent linkage, solve patent disputes through judicial litigation and grant a certain period of market exclusivity to first generic drugs which has made breakthrough in patented technology. As the sole expert invited in the industry, PhIRDA's leader attended the Coordination Meeting of the State Council on the Reform of Drug IPR System chaired by Wang Yang, the vice premier of the State Council, in May 19, 2017 at Zhongnanhai. This has attracted great attention, PhIRDA presented professional suggestions to promote the central government's recognition of China's exploration in drug patent linkage system and trial implementation of patent-term compensation system. The meeting laid a foundation for the *Opinions on Deepening the Reform of the Review and Approval System and Encouraging Innovation in Medical Devices* (Ting [2017] No. 42, hereinafter referred to as 'Document No.42') issued by the General Office of the CPC Central Committee and the General Office of the State Council in October 8, 2017. The aforesaid 8 recommendations have been included in Document No.42.

② Proposed a drug intellectual property system in line with national conditions

Entrusted by the former CFDA, PhIRDA drafted the revision proposals and amendments regarding the intellectual property clauses of the *Drug Administration Law.* PhIRDA proposed the establishment of drug patent linkage system, improvement of data protection system, and

market exclusivity for generic drugs with patent breakthroughs, and also provided recommendations on how to implement the drug patent linkage and trial patent-term compensation. These research results were conducive for China to explore patent linkage system and implement patent-term extension system.

③ Proposed suggestions for the amendment draft of the *Drug Administration Law*

PhIRDA repeatedly proposed suggestions for the *Drug Administration Law* (*Amendment Draft*) (*hereinafter referred to as* '*Drug Administration Law*'). On May 6, 2019, the Director of the Administrative Law Office of the Legislative Affairs Commission of the NPC Standing Committee visited PhIRDA and listened to comments from PhIRDA representatives and members on the *Drug Administration Law*. PhIRDA's suggestions "permitting the establishment of regional and central ethical committee to improve the efficiency of ethical review, encouraging the development of the drugs for rare diseases and pediatric drugs, etc." have been incorporated by the *Drug Administration Law* deliberated and passed by the NPC Standing Committee.

④ Proposed a report on the recommendations for improving the Drug Registration Fee System to support the legislation of drug registration fee

Some enterprises reflected heavier burden on enterprises caused by drug registration fee to the inspection group for the 'Joint Committee of the Department of Lighter Enterprise Burden of the State Council', and recommended cancellation or suspension of the charge. In response to this, PhIRDA accepted the entrustment of the NMPA and organized PhIRDA members and experts to hold discussions. In combination with PhIRDA's systematic research on international drug registration fee system, PhIRDA formed a report with the recommendations for improving the system, such as legislation to clarify drug registration fee only for performance evaluation and combining and supplementing charge to lessen corporate burden. The report was highly valued by the leaders of the NMPA, which specially instructed relevant departments and offices to provide a formal reply letter with supplementary comments. The report was officially submitted to relevant departments such as the National Development and Reform Commission (NDRC) and the Ministry of Finance.

(2) Proposed the improvement of drug review and approval regulations

①Proposed a new classification of chemical drugs for registration

On May 22, 2015, PhIRDA took the initiative to propose a new classification of chemical drugs for registration, which was approved by the CFDA. Subsequently, PhIRDA accepted several times entrustment from the Department of Drug Registration of NMPA and put forward suggestions for detailed classification of chemical drugs for registration and corresponding technical requirements. The classification proposal was reflected in the *Opinions on the Review & Approval System for Drugs and Medical Devices* (SC [2015] No. 44) issued by August 18, 2015, providing the basis for the scientific review of drugs.

② Suggestions for the verification of clinical trial data

In December 2015, the CFDA held an exchange meeting on 'The Way to Orderly Self-examine and Inspect Clinical Trial Data', soliciting opinions from the industry and clinical institutions for the comprehensive national verification. After the meeting, PhIRDA drafted and submitted to the CFDA the *Proposal on Orderly Advancing the Verification of Clinical Trial Data and Properly Implementing Clinical Trials*. The document specified the establishment of the clinical trial operation mechanism under the GCP, less restriction on the prior qualification review of clinical trial institutions, as well as the establishment of national and local responsibility division supervision system with riskcontrol as the core. The opinions for sound industry development was highly acclaimed by pharmaceutical community and CFDA leaders. Since the initiation of clinical data on-site verification, PhIRDA has effectively promoted the reconstruction of China's drug research and development ecology.

③ Suggestions on canceling the monitoring period for new drugs and improving the protection system of drug research data

Being entrusted by NMPA, PhIRDA conducted a research on whether the monitoring period of new drugs should be canceled in the amendment of the *Drug Registration Administration Regulation*. PhIRDA suggested to cancel the monitoring period for new drugs, implement and improve of China's protection system of drug research data.

④ Suggestions on drug registration management measures and corresponding supporting technical regulations

Being entrusted by NMPA, PhIRDA engaged in the revision of two parts ('Clinical Trials' and 'Marketing Authorization') of the *first amendment of the Drug Registration Administration Regulation*. PhIRDA organized members and experts to collate the technical documentsrelated to the law and proposed the catalogues of the documents for revision, so as to guarantee the synchronous revision of the law and supporting documents.

PhIRDA also offered suggestions for the *Administrative Regulations on the On-site Inspection on Drug Registration (Draft for Comment)*

and the *Requirements for the Application Materials for Quality & Efficacy Consistency Evaluation on Marketed Chemical Generic Drugs (Injection) (Draft for Commen)* and drafted the *Clinical Technical Registration Requirements for Class 3 Chemical Drugs.*

⑤ Suggestions for promoting the development of China's innovation of biological products

Entrusted by NMPA, PhIRDA concluded a proposal report on reforming the classification of biological products for registration, optimizing approval procedure, encouraging the development of biosimilar drugs, technical reviews and on-site inspections, and verifying the marketing of batch products for process certification. PhIRDA was invited to attend the 'China Biological Product Innovative Development Forum' held by NMPA, delivering a speech on promoting the standardization, scientification and efficiency of drug supervision. Jiao Hong, NMPA Commissioner, based on PhIRDA's opinion, directed the CDE to call together relevant departments to study the revision of relevant laws.

(3) Suggestions for revision of other laws and regulations related to drug administration

Invited by the NPC Education, Science, Culture and Public Health Committee, PhIRDA attended the seminar for the *Vaccine Administration Law of the People's Republic of China (Draft for Comment)*. PhIRDA voiced constructive opinions on how to define the legal relationship between vaccine administration law and drug administration law, optimize the review on vaccine clinical trials, expand the scope of batch approval and inspection institutions for biological products, and solve key issues on vaccine supervision such as storage and distribution temperature.

With respect to the *Amendments to the Patent Law of the People's Republic of China (Draft)* deliberated by the 7th Session of the Standing Committee of the 13th NPC, PhIRDA drafted the report for the Legislative Affairs Committee of the Standing Committee and recommended patent-term compensation for all the innovative drugs under the application and registration in China (not necessary to concurrently apply for marketing at home and abroad), so as to promote local innovation. The suggestions won positive response.

2. Suggestions for improving the healthcare system and drug access mechanism in China

(1) Suggestions for establishing a healthcare system with Chinese characteristics

PhIRDA attended the 'Medical and Health System Reform Seminar' organized by the Ministry of Human Resources and Social Security on January 26, 2016 and the 'Comprehensively Establishing a Healthcare System with Chinese Characteristics Seminar' by the health insurance bureau on August 15, 2018. PhIRDA suggested the authorities to advance the linkage between medical treatment, medical insurance and drugs, establish more active payment system for medical insurance drugs, comprehensively review the adjustment of the National Drug Reimbursement List, etc, which were highly valued by the leaders of the two authorities.

(2) PhIRDA also tabled a proposal on the adjustment of the 2017 and 2019 National Drug Reimbursement List. PhIRDA leader participated in the adjustment as consulting expert and recommended incorporating eligible new drugs and high-quality generic drugs into the alternative list, giving full play to our role as industry association.

(3) Suggestions for improving the dynamic adjustment mechanism of the NDRL and the principles of drug price negotiation covered by medical insurance

Being entrusted by the former Medical Insurance Department of the Ministry of Human Resources and Social Security, PhIRDA put forward suggestions for the principle of drug price negotiation, including setting the overall value and cost performance of drugs as main evaluation basis, adoption of diversified and multi-class negotiation strategies, no second provincial-level negotiation for negotiation varieties, and making direct online bidding and procurement over the drugs within negotiation term. Most of our recommendations were adopted in the drug price negotiation over medical insurance drugs.

(4) Suggestions for the national pilot work plan for centralized drug procurement

With respect to the national pilot work plan for centralized drug procurement passing the quality consistency evaluation of generic drugs (hereinafter referred to as 'Centralized Drug Procurement Pilot'), PhIRDA offered our suggestions on the principle of pilot work, scope of varieties, way of bidding and procurement, development of medical insurance payment standards, etc.

In response to the '4+7 Centralized Drug Procurement' policy, some academicians of the Chinese Academy of Sciences and the Chinese Academy of Engineering and PhIRDA representatives took the lead in co-authoring a comprehensive report on the Centralized procurement Pilot Project and submitted it to the Central Committee for Deepening Overall Reform and General Secretary Xi Jinping. China's pharmaceutical industry is in the period of structural transformation and adjustment when the input for innovative drug development by companies mainly came from the sales profit of generic drugs. According to the report, the state should cast away a bidding model with focus on low cost and sole suppliers, divert the costs saved during circulation to the varieties passing the consistency evaluation, so as to motive

enterprises to think out of box and improve the quality of generic drugs. In the recent second round of national drug centralized procurement plan, the principle of sole successful bidder has been changed as the maximum 3 successful bidders on the base of lowest price (provisional). PhIRDA also launched research study on hot topics such as incorporation of innovative drugs into the medical insurance coverage, reasonable payment prices, achievement transformation, and patient benefits, to provide solutions for the medical insurance department on how to establish an access mechanism for innovative drugs based on national conditions.

3. Voiced opinions and suggestions on improving the quality of generic drugs in China at the biweekly consultation symposium of the CPPCC National Committee

PhIRDA leader was invited to attend the 43rd biweekly consultation symposium of the CPPCC National Committee chaired by Yu Zhengsheng, the standing committee member of the Political Bureau of the CPC Central Committee and the chairman of Chinese People's Political Consultative Conference. Along with some members of national committee of CPPCC, experts and scholars, and the relevant ministerial and departmental leaders of the State Council, PhIRDA leader suggested that China's drug bidding and use policies must be improved to establish normative market environment for high-quality generic drugs and promote the preference to their clinical use. The CPPCC specially included PhIRDA's advices into the brief report and submitted it to the central government, and were mentioned by the subsequently issued policy documents of the state.

4. Other suggestions on improving the mechanism of drug use and procurement in China

(1) The special research proposal for the drug bidding & procurement system was adopted by Document No.7 of the State Council

At the end of 2014, PhIRDA drafted a report with focus on the downsides and hazards of the 'Lowest Bidding Price' specified in the drug bidding & procurement system and submitted it to the leaders of the State Council as well as relevant departments such as the National Health and Family Planning Commission and the Medical Reform Office of the State Council. In the *Guiding Opinions on Improving the Centralized Drug Procurement in Public Hospitals* (hereinafter referred to as 'Document No.7 of the State Council'), the guiding ideology of combining biding and procurement, linking quantity and price, improving double-envelop bidding system, and classified procurement reflected the expectations of PhIRDA and peers of the industry.

(2) Proposed recommendations for improving centralized drug procurement for the Central Committee of Chinese Peasants and Workers Democratic Party and won the approval of the State Council's leaders

In April 2015, the *Research Report on Improving the Centralized Drug Procurement Mechanism of China* drafted by PhIRDA with the entrustment of the Central Committee of Chinese Peasants and Workers Democratic Party won the recognition from Academician Chen Zhu, the chairman of the said party and vice chairman of the NPC Standing Committee. It was also included in the party's *Suggestions for Improving the System of Core Drugs in Medical and Health Institutions and Realizing Good Performance in Centralized Drug Procurement* as core content and then submitted to leading comrades of the State Council. The leaders instructed the National Health and Family Planning Commission and the Ministry of Human Resources and Social Security to read and study the documents. Relevant parties should also mobilize all the forces to realize the combination of bidding and procurement and linkage between quantity and price, and avoid unreasonably high prices. Those elements should be considered while collating and revising the National Drug Reimbursement List.

5. Assessed the impact of China-US trade friction on China's biomedical industry

In November 2018, being entrusted by the Ministry of Industry and Information Technology, PhIRDA were studying the impact of China-US trade friction on China's biomedical industry, in an attempt to identify solutions through the evaluation. The results of the survey and phased research showed that the current China-US trade friction affected medical talent exchange, technical cooperation, clinical trials conducted in US, market development and financing among others. Next, PhIRDA will focus on this topic and seek development strategy to grapple with the current challenge.

(II) Resolutely safeguarded the legitimate rights and interests of PhIRDA members and industries, constantly called for sound development of the industry

1.Suggestions for timely correction of drug bidding and procurement led by the health departments of some provinces

PhIRDA promptly studied the problems of drug bidding and procurement policies of Hunan, Bengbu (Anhui Province), Zhejiang, Fujian and other provinces and cities and formally published documents to offer suggestions, which were responded by a majority of drug procurement departments. The head of the Hunan Provincial Drug Bidding Office criticized us and threatened to file a lawsuit. PhIRDA released claims on the official website to bring out the facts and reasons and reiterate our opinions and suggestions for the office. The action attracted the

attention of the industry and drug bidding departments across the country. PhIRDA was highly acclaimed for the boldness in holding firmly to the truth and speaking from a sense of justice. On the other hand, Bengbu Municipal Health and Family Planning Commission violated the central government's requirement for encouraging innovation, streamlining administration and delegating power to the lower levels, and allowing market to play a decisive role in resource allocation in the process of drug procurement. It was even suspected of violating such laws as the *General Principles of the Civil Law*, the *Contract Law* and the *Antitrust Law*. Given this, PhIRDA reported to the National Development and Reform Commission and the former State Administration of Industry and Commerce. The higher commission issued the *Correspondence of the General office of the National Development and Reform Commission on Suggesting the Correction of Administrative Power Abuse by the Bengbu Municipal Health and Family Planning Commission to Eliminate Restrictions on Competition* (Fa Gai Ban Jia Jian [2015] No. 2175, hereinafter referred to as 'Document No. 2175'), disapproving the wrongdoing. This is the first anti-monopoly investigation involving medical reform initiated by the National Development and Reform Commission in accordance with the law. It has played a guiding and demonstrative role in drug procurement throughout the country.

2. Suggestions for delayed clinical trials caused by the examination and approval system of human genetic resources

The original examination and approval system of human genetic resources took up a large portion of clinical trial time, resulting into significant delay in clinical trials and poorer drug accessibility. PhIRDA suggested to simplify the examination and approval process and only register the tests with a limited number of samples with administrative department of science and technology of the State Council. The proposal was embodied in the *Regulations of the People's Republic of China on the Management of Human Genetic Resources (Order No. 717).*

(III) As an independent third party, undertook the evaluation on the implementation performance of the 'Major New Drugs Development' of the '11th Five-Year Plan' and '12nd Five-Year Plan'

Being entrusted by the National Health and Family Commission, PhIRDA, as a third-party organization, evaluated the implementation performance of National Science and Technology Major Project for 'Major New Drugs Development' (hereinafter referred to as 'Major Project') of the '11th Five-Year Plan' and '12nd Five-Year Plan'. PhIRDA invited 29 well-known clinical, pharmacy, and pharmacoeconomic experts to form a special evaluation expert committee, and developed an evaluation index system oriented in quantitative objective data indicators and supported by qualitative ones. Through the reporting of major projects, field visit and on-site assessment, PhIRDA summarized the highlights and work results and put forward loads of constructive suggestions on improving special operation management model. The National Health and Family Planning Commission officially printed the assessment report.

(IV) Conducted research on other topics

In the past five years, PhIRDA has launched independent studies on hot issues in the field of China's pharmaceutical policy and set foot in the United States, France, Germany and Japan for investigation and study. By studying and drawing upon the systems and experience of developed countries and regions for supporting pharmaceutical innovative development, PhIRDA laid a foundation for Chinese policies and systems encouraging drug innovation. Over 10 study projects are under research or already successfully concluded by PhIRDA, covering drug bidding & procurement, drug registration fee system, reform of drug price management system, industry development of generic industries, access to medical insurance coverage for innovative drug, formation mechanism of medical insurance payment standards, relevant systems of intellectual property protection, etc.

(V) Promoted the development of rare diseases

PhIRDA, Peking Union Medical College Hospital, Chinese Hospital Association, Chinese Research Hospital Association, etc. jointly established the China Alliance for Rare Diseases (hereinafter referred to as the 'Alliance'), and PhIRDA was elected as vice chairman unit. PhIRDA participated in the organization of the Compendium of China's First List of Rare Diseases, the *Guidelines for Diagnosis and Treatment of Rare Diseases (2019 Edition)* to initiate the relevant selection work for the second list of rare diseases.

IV. Announced China's pharmaceutical innovation to the world by organizing Selection Activities, releasing articles in authoritative journals, accepting interviews with authoritative media, etc.

(I) Organized the selection activities of drug innovation brand to discover the most valuable innovative drugs and commend the most influential innovative people

In 2015, PhIRDA launched the 'Selection Activities of China Pharmaceutical Innovation', in an effort to fully implement the strategy of

the Party Central Committee and the State Council on innovation-driven development and brand-led innovation. In 2018, the event was launched with the cooperation from the Suzhou Industrial Park, and the name was changed as 'Dushu Lake Prize' Selection Activities of China Pharmaceutical Innovation Brand (hereinafter referred to as 'Selection Activity'). By drawing on international selection rules for scientific awards, the event initially met significant clinical requirements with pharmaceutical innovation activities/results and determined the contributions to the social and economic fields as main evaluation indicator. In addition, it established the industry's most authoritative review expert committee covering the most areas (56 members including 17 academicians) by inviting a multitude of renowned clinical and pharmaceutical experts, including those from Chinese Academy of Sciences and Chinese Academy of Engineering, as well as foreign countries. This laid a solid foundation for enhancing the scientific authority and fairness. It is a non-profit public welfare activity and does not charge any fee. So far, it has been successfully held for three times. For 2019 Selection Activity, award nomination has been completed, singling out 13 projects for drugs and figures. The award ceremony for the 4th Brand Selection will be held on the evening of September 21 at Broadcasting Hall of Suzhou Broadcasting System (SBS).

(II) Issued an article in the Nature to showcase the achievements of Chinese pharmaceutical innovation, being recognized by the leading comrades of the State Council and granted with the 'Award for Top 10 News for Medical Science and Technology'.

PhIRDA organized experts to draft a collection of articles '*PhIRDA: From imitator to innovator'* in the Nature. It is the first time for China to demonstrate the remarkable pharmaceutical achievements from imitation to innovation in the past decade. Deputy Prime Minister Liu Yandong specially gave us credit. The articles was rated as the '2017 Award for Top 10 News for Medical Science and Technology' by the News of Chinese and Overseas Medical Science and Technology founded by the Health News as well as the Chinese Medical Association, Chinese Academy of Medical Sciences, and the Science and Technology Development Center of National Health and Family Planning Commission.

(III) PhIRDA leader accepted various media interviews at home and abroad to promote the achievements of Chinese pharmaceutical innovation

PhIRDA leader accepted the interview of the program, *Topics in Focus - New Drug Approval on Fast Track*, and introduced China's pharmaceutical development and the result of the reform of drug review and approval system. It was the first time that the association was interviewed by the *Topics in Focus*, which signified high affirmation of our efforts for the drug supervision reform.

More than once, PhIRDA leader also accepted interviews by Chinese and foreign authoritative media such as the *CCTV News Week, People. cn, Pharmaceutical Executive, Prism* of Tencent News, as well as *South China Morning Post*, promoting new development of China's pharmaceutical industry and drug supervision reform.

V. Created an inclusive and dynamic investment environment for pharmaceutical innovation

(I) Founded the China BioMed Innovation and Investment Conference

The China BioMed Innovation and Investment Conference (hereinafter referred to as the CBIIC), founded by PhIRDA, is China's first platform for diversified achievement transformation and international cooperation & exchange with extensive influence and authority. The previous three conferences attracted a total of over 65,000 participants including over 1,000 investors and more than 1,500 pharmaceutical innovation companies. The conference featured the clinical data global release for 25 innovative drugs and the roadshow of over 320 projects (enterprises).

The 2019 CBIIC was held in Suzhou Industrial Park from September 21 to 23, 2019. The conference invited relevant leaders of national drug administration to interpret newly revised *Drug Administration Law*. The world's top drug development scientists and four renowned stock exchanges (NASDAQ, HKEX, London Stock Exchange Group and Shanghai Stock Exchange) gathered in China and held heated discussionover the financing support by the global platform of pharmaceutical innovation and innovative financing as well as future development trends. On the basis of previous events, the conference added new special roadshows, including Service Agencies Roadshow, Service Company Roadshow, SSE STAR Market Forum, WIT-MED + Big Data Roadshow, Artificial Intelligence (AI) + BioMed Roadshow, International Oncology Company Roadshow, etc. It aimed to promote the achievements of pharmaceutical innovation, development of industry policies, domestic and international cooperation in research projects, and to attract social capital for innovation.

(II) Deeply participated in the innovation and reform of Hong Kong's capital market

In 2018, Hong Kong Exchanges and Clearing Limited (hereinafter referred to as 'HKEX') reformed the Listing Rules for the main board. During the public consultation stage, PhIRDA conducted in-depth exchanges with the HKEX and signed a Memorandum of Understanding.

PhIRDA's suggestion - allowing pre-revenue biotech companies list in Hong Kong - was adopted. 5 PhIRDA experts, including Song Ruilin, Executive President of PhIRDA, and Tian Yuan, Chairman of PhIRDA Pharmaceutical Innovation Investment Specialty Committee were appointed as the Biotech Advisory Panel Member for the Stock Exchange of Hong Kong Limited. 6 out of the 7 not-profitable-yet biotech companies that have been listed in Chinese Hong Kong are PhIRDA members. In the first half of this year, among the world's top 10 biotech IPOs, 5 has been listed in the HKEX and 2 (Hansoh Pharma and Cstone Pharmaceuticals) are PhIRDA members. In particular, Hansoh came out top in the 2019 list of the world's top 10 IPOs in the first half of this year. The new policy of HKEX is significant to enhance market activity and solidify the role of global biotechnology financing platform.

In addition, during the 2019 CBIIC, PhIRDA held HKEX & Innovative Pharmaceutical Companies Forum to continuously exchange views on the development of the Chinese Hong Kong's capital market.

(III) Motivated the Science and Technology Innovation Board of the Shanghai Stock Exchange (SSE STAR Market) to finance pharmaceutical innovation

Shanghai Stock Exchange (hereinafter referred to as 'SSE') set SSE STAR, signifying that Chinese pharmaceutical innovation enterprises have another choice, in addition to NASDAQ and HKEX. PhIRDA member, Chipscreen, became the first innovative company to list in SSE STAR Market and set a new high in PE ratio for the first day.

At the 2019 CBIIC, the themed SSE STAR Market Forum was also initiated, so that the SSE could promote relevant new policies and provide exchange and cooperation opportunities for innovative pharmaceutical companies to get listed in the board.

VI. Launched international exchange of pharmaceutical industry

(I) Actively joined international organizations and encouraged Chinese innovation achievements to be present in international arena

PhIRDA, as the sole representative of Chinese local pharmaceutical companies, joined the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) and accepted the invitation to become one member of the Asia Partnership Conference of Pharmaceutical Associations (APAC). It assisted China in developing international drug regulatory standards and promoting international exchange and cooperation on pharmaceutical innovation.

(II) Communicated with foreign embassies in China, foreign pharmaceutical profession association and international organizations to present ideas and make contributions on behalf of China

1. PhIRDA has established close connection with the embassies and consulates of the United States, United Kingdom, Netherlands, Canada, etc. in China and over 40 institutions such as the World Health Organization, World Trade Organization, World Intellectual Property Organization, IFPMA, Pharmaceutical Research and Manufacturers of America (PhRMA), Biotechnology Industry Organization (BIO), National Foundation for Cancer Research(NFCR), European Federation of Pharmaceutical Industries and Associations (EFPIA), Japan Pharmaceutical Manufacturers Association (JPMA). PhIRDA jointly launched several activities and helped PhIRDA members develop better understanding of the supervision system in respective countries.

2. In the past five years, PhIRDA organized delegations to visit government departments, research institutes, pharmaceutical innovation companies and industry associations in the United States, Germany, Netherlands, Switzerland, France, Australia, Japan, Israel, etc., gaining an in-depth understanding of the countries that encourage pharmaceutical innovation policies and globally leading innovative research results, strengthening industrial cooperation and provide service and support for international market expansion.

3. In the past five years, PhIRDA has been invited to the J.P. Morgan Healthcare Conference, Asia Partnership Conference of Pharmaceutical Associations (APAC), BRICS Health Ministers Meeting, APEC Business Ethics for SMEs Forum, and international conference on innovation, investment, and administration. PhIRDA introduced China's development of pharmaceutical innovation and studied the advanced regulatory experience from other countries and regions.

4. PhIRDA have subsequently cooperated with the Eliminate Cancer Initiative (ECI), NFCR, Chinese American Hematologist and Oncologist Network (CAHON), BIO, R&D-based Pharmaceutical Association Committee (RDPAC), Suzhou Industrial Park Administrative Office (SIPAC), Beijing Tiantan Hospital of Capital Medical University, etc., and held meetings such as the 'Forum of National and International Pharmaceutical Innovation Cooperation - Challenges and Opportunities for BRICS, China-US Seminar on Cooperation in Biomedical Innovation', and 'SINO-U.S. Oncology Experts Roundtable', to play a positive role in further expanding international exchanges and cooperation.

(III) Actively participated in the formulation of international rules and provided decision-making suggestions for the government

Being entrusted by the ICH Working Office of National Medical Products Administration, PhIRDA repeatedly organized relevant guideline training and comments from members for 53 ICH guidelines. Being entrusted by IFPMA, PhIRDA have recommended 30 experts (including 11 team leaders and 6 alternate leaders) to 15 ICH Expert Working Groups (EWGs) of the IFPMA, who have engaged in the development and implementation of the ICH guidelines. There are 29 domestic EWGs under ICH Working Office, PhIRDA have recommended 16 experts to 10 EWGs.

VII. Continuously improved the ability of medical information service

(I) Collected and organized the latest news of the pharmaceutical industry

PhIRDA adhered to collecting, editing and collating the latest news of pharmaceutical industry and compiling the *Daily Pharmaceutical Information Brief*. PhIRDA provided the latest information about industry development and policy for members, industry experts, government departments and cooperative institutions and published them on the official website.

(II) Convenient communication via WeChat to release information

PhIRDA initiated the WeChat official account and service account for the CBIIC. With the we-media platform, PhIRDA have widely promoted our suggestions for pharmaceutical policies and pushed current information, arousing wide concern in the industry. Up to now, PhIRDA have accumulated more than 10,000 followers of the two accounts.

All representatives, through five years of hard work, PhIRDA have reaped achievements and made breakthroughs, gradually strengthening our influence in the pharmaceutical industry at home and abroad. All of this is inseparable from the joint efforts of members and the support from all sectors of society. I would like to express my heartfelt gratitude to the leaders of our respective departments, experts and members for long-term support.

Although PhIRDA have achieved some achievements, PhIRDA must be soberly aware there are still many problems to solve for innovative development. The work capacity and service level of the Secretariat have to be improved, and our activities need be further innovated and improved in terms of content and pattern. Next, PhIRDA will earnestly sum up experience based on existing work, systematically study the pain spots of industrial development and our development position. In this way, PhIRDA will fully improve the strength of our comprehensive service, better adjust to the new situation of reform and development, and realize the common development of ourselves, members and the industry.

Part II. Work Proposal for the 11th General Assembly (2019-2024)

In the past five years, China's pharmaceutical industry has changed astoundingly. If it is fair to say implementation of innovation encouraging policies including the reform of drug review and approval, pilot for marketing authorization holder (MAH) system, has advanced industrial development, a series of measures including consistency evaluation on generic drugs, drug traceability responsibility system, and policy for medical insurance control fee and financial verification of pharmaceutical enterprises signal strict regulation and transition to high quality. Pharmaceutical innovation entails global cooperation. Against the overall downturn of the world economy, turbulent global changes and increasingly fierce unilateralism and trade protectionism, the capital market fell into a tight corner because of difficult fund-raising and investment. The exchange of talents and technology has been blocked, and China's pharmaceutical innovation and development faces morechallenges. It is particularly for PhIRDA, members and the industry to adhere to innovation-driven development and to quickly realize the conversion between new and old energy. In the future, PhIRDA will aim at the key issues that restrict the development of pharmaceutical innovation and focus on how to promote the construction of mechanisms and systems suitable for high-quality innovation and development. By further expanding cooperation areas and establishing connection and partnership with relevant governments, industrial departments and organizations, PhIRDA will promote the continuous optimization of the ecological environment of the pharmaceutical industry, support the cultivation of new market advantages, and contribute to the sustainable and healthy development of pharmaceutical industry. The work proposals are detailed as follows:

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

The 19th National Congress of the Communist Party of China has put forward clear requirements for social organizations in terms of social governance, deliberative democracy, and grassroots party organization construction. It is necessary to build social organizations into an important force for consolidating the Party's power. PhIRDA will input more efforts in theoretical study by Party members, train and attract outstanding backbones, strengthen the Party's leadership over our business, rendering Party building to closely integrate with the key work of the society and realizing mutual progress.

II. Fully cooperate with the superior competent authorities to secure the implementation of decoupling reform

The decoupling from administrative bodies and industrial associations/chambers of commerce is a great decision of the Party Central Committee and the State Council under the guidance of the socialism thought with Chinese characteristics in the new era led by Xi Jinping. PhIRDA will unswervingly implement the requirements of 10 departments including National Development and Reform Commission, Ministry of Civil Affairs, and Organization Department of the CPC Central Committee and so on, under the *Implementation Opinions on the Decoupling Reform between Administrative Bodies and Industrial Associations/Chambers of Commerce*, and fully engage in '5 Separations and 5 Norms, to ensure smooth, prompt, and efficient completion of decoupling reform.

III. Join poverty alleviation cause and resolutely fight against poverty

PhIRDA will engage in poverty alleviation cause. It is only an important responsibility for us but also an indicator for serving the country, society, masses, and industry. PhIRDA will thoroughly study and implement General Secretary Xi Jinping's important strategic thinking on poverty alleviation and development, conscientiously put into place decision-making arrangements of the Party Central Committee and the State Council, and set targeted poverty alleviation an important task for current and future period. Meanwhile, PhIRDA will lead members to give full play to advantages in capital, technology, market, management, etc., focus on 'industrial poverty alleviation', 'education for poverty alleviation', 'health for poverty alleviation' and 'voluntary poverty alleviation', etc. Anyway, PhIRDA will be devoted to getting rid of poverty and realizing a moderately prosperous society.

IV. Launch study on major medical policies, offer suggestions for the relevant government department

In the long run, innovative development capability will be the core competitiveness of industry and enterprise development, and a sound policy environment is of paramount importance. PhIRDA will make full use of the wisdom and resources of experts in the industrial think tank to conduct special studies on pain points and difficulties affecting innovative development of the industry. This will enable us to offer suggestions to government departments, members and even the industry.

(I) Seriously publicize and implement the *Drug Administration Law*, organize forces to study the implementation rules and supporting policies for the law, offer constructive suggestions to the relevant department in an attempt to ensure the smooth implementation of the reform policies on China’s drug administration.

(II) PhIRDA will cooperate with the Research and Development International (RDI) to study the strategy of promoting the export of the products of domestic pharmaceutical enterprises through the Belt and Road Initiative (BRI) and pave the way for Chinese Pharmaceutical enterprise’s rapider access to international market.

(III) Building closer contact with the ministries and commissions of drug administration, launch study on major policies affecting industrial development independently or upon entrustment, report industrial development and studies to the relevant central departments, fully fulfilling the responsibility for service, coordination and supervision in terms of government decision-making.

(IV) Establish extensive contact with domestic pharmaceutical industry organizations or relevant units, jointly promote major themed studies in the pharmaceutical industry, publish the research report on industrial development or blue book, enabling the society to better understand the industry and creating favorable conditions for improved industry development environment.

V. Constantly blaze new trails in a pioneering spirit, leading the innovation and development of PhIRDA members and the industry

(I) Deeply participated in the pilot work for the reform of SSE STAR Market

Based on existing work, PhIRDA will continue to pay constant attention to the relevant policies of SSE STAR Market, actively cooperate with the China Securities Regulatory Commission and the Shanghai Stock Exchange, organize the pharmaceutical innovation enterprises to get public in the SSE STAR Market, industry experts and scholars to hold irregular symposiums and constantly make proposals for the board's smooth operation.

(II) Hold successful brand activities

PhIRDA will constantly blaze new trails in a pioneering spirit and expand our service contents. PhIRDA will strive for successful brand activities such as the China Cardiovascular Disease Clinical Research Quality Management Standard (GCP) Conference, China Hospital Pharmacy Policy Forum, and CBIIC and to make the activities keep pace with the times.

(III) Initiate the establishment of the Pharmaceutical Innovative Development (Suzhou) Foundation

PhIRDA will actively promote the registration of the Pharmaceutical Innovation and Development Foundation (Suzhou) (hereinafter referred to as the 'Foundation'). In the future, PhIRDA will jointly organize the 'Dushu Lake Prize' Selection of China Pharmaceutical Innovation Brand with the Foundation, explore the Foundation's role in the fields of charitable drug donation and poverty alleviation, expand fund-raising channels, and build it as a new push in boosting the innovation and development of the pharmaceutical industry in China.

(IV) Seize development opportunities of the Guangdong-Hong Kong-Macao Greater Bay Area, promoting the development of biomedical industry

In accordance with the spirits of the *Development Plan for Guangdong-Hong Kong-Macao Greater Bay Area* of the Central Committee of the Communist Party of China and the State Council and the *Opinions on Supporting Shenzhen* in Building a *Pilot Demonstration Area of Socialism with Chinese Characteristics*, PhIRDA entered into an cooperation with the People's Government of Pingshan District, Shenzhen Municipality to jointly promote China's pharmaceutical innovation and to co-build a highland for biological medicine in the bay area. In the future, PhIRDA will work with People's Government of Pingshan District to integrate bioindustry innovation resources with global vision, deepen cooperation through high-end conferences, investment promotion, and introduction of innovative projects, and strive to make positive contributions to China's pharmaceutical innovation.

Besides, PhIRDA will continue to actively participate in the work related to the China Alliance for Rare Diseases, and go extra miles to promote the improvement of relevant policy environment and accelerate the construction of the strategic system for rare disease prevention and management.

VI. Continue to expand channels and space for international cooperation and strengthen international exchanges

(I) Continue to play the role of think tank, recommend and organize experts to participate in ICH working groups and guideline revision

PhIRDA will continue to follow the requirements of the IFPMA-ICH Secretariat and CDE, recommend authoritative experts in relevant professional fields to participate in the development and revision of the ICH technical guidelines, become an active part of the developmentof international standards and rules. PhIRDA will also organize training on the transformation and implementation of the ICH guiding principles, promoting the internalization of the development and risk management and enhancing the innovation and international competitiveness of China's pharmaceutical enterprises.

(II) Establish innovative R&D cooperation mechanism with relevant institutions at home and abroad and organize international exchange activities, jointly upgrading China's pharmaceutical innovation to international level

PhIRDA will continue to expand the industrial exchanges and cooperation with the embassies, consulates, government agencies and industry associations in China, in terms of scientific research, clinical, industry, policy etc. The initiative aims to seek overseas cooperation opportunities for members, promote China's integration with the world in trade, investment, technology, etc. and jointly build an international communication platform for pharmaceutical innovation.

VII. Optimize internal governance structure, strengthen the construction of Specialty Committees and the Secretariat, and enhance the comprehensive capabilities

In the five years to come, PhIRDA will further optimize internal governance structure and strengthen the construction of the Secretariat; reform existing Specialty Committees and set up the Consultant Committee. PhIRDA decides to newly establish Specialty Committee in the fields of cardiovascular, oncology, cranial nerve and pharmacy to attract high-caliber talents and provide more quality service for PhIRDA member and the whole industry; innovate information service model to provide timely and quick policy and industrial information for the government, PhIRDA members and industrial peers; comprehensively improve internal management systems, strengthen integrity and self-discipline, and hold open, transparent, standardized and democratic meetings.

All the representatives, China’s pharmaceutical industry has entered an era of integration and transformation. The way ahead is long, and only innovation can work for us. PhIRDA will keep to focus on our principle of 'innovation, industrialization and internationalization', enrich and expand services and unite and mobilize members. As the bridge between the government and industry, PhIRDA will enhance self-discipline, safeguard legal rights and interests of PhIRDA members. PhIRDA will remain committed to promoting the innovation and sustainable development of China's pharmaceutical industry, safeguarding the health of the masses, and realizing the objective of 'Two 100 Years' and China Dream, and great rejuvenation of the country.

The aforesaid report is expected to be deliberate.

专业委员会简介

根据工作需要，经中国医药创新促进会（以下简称"中国药促会"）第十届一次、二次、四次和第十一届会员大会审议通过，批准成立药物研发、药物临床研究、医药政策、医药创新投资、创新研发服务、医药企业合规、心血管药物临床研究、脑神经药物临床研究、抗肿瘤药物临床研究等专业委员会。

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

心血管药物、脑神经药物、抗肿瘤药物和药物临床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。

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

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

Introduction of Specialty Committees

According to the First, Second and Fourth Meeting of 10th and the First Meeting of 11th PhIRDA General Assembly, China Pharmaceutical Innovation and Research Development Association (PhIRDA) approved the establishment of the following Specialty Committees: Drug R&D, Clinical Research, Medicinal Policy, Pharmaceutical Innovation Investment and Innovation R&D Services, Ethics and Business Compliance, Clinical Research on Cardiovascular Drugs, Clinical Research on Cranial Nerve Drugs, Clinical Research on Oncology Drugs etc.

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

Clinical Research on Cardiovascular Drugs, Cranial Nerve Drugs, Oncology Drugs Specialty Committees and Clinical 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.

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

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

第二届药物研发专业委员会

The 2nd Drug R&D Specialty Committee

名誉主任委员　蒋建东

中国医药创新促进会
2017-2018年度会长
中国医学科学院药物研究所所长

Honorary Chairman, Jiang Jiandong
2017-2018 Annual Chairman of China Pharmaceutical Innovation and Research Development Association (PhIRDA)
Director of Institute of Materia Medica, Chinese Academy of Medical Science

主任委员　王印祥

北京加科思新药研发有限公司董事长兼CEO

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

副主任委员　张 丹

方恩医药发展有限公司董事长兼CEO

Vice-Chairman, Zhang Dan
Chairman of the Board & CEO of Fountain Medical Co., Ltd.

副主任委员　陈建峰

中国工程院院士、中国工程院秘书长、北京化工大学副校长

Vice-Chairman, Chen Jianfeng
Academician of the Chinese Academy of Engineering, General Secretary of the Chinese Academy of Engineering, Vice President of Beijing University of Chemical Technology

副主任委员　房健民

荣昌生物制药（烟台）有限公司
总经理兼首席科学官

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

副主任委员　何 伟

浙江导明医药科技有限公司总经理

Vice-Chairman, He Wei
General Manager of DTRM Biopharma

副主任委员　鲁先平

深圳微芯生物科技股份有限公司
董事长、总裁

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

副主任委员　徐希平

深圳奥萨医药有限公司董事长兼首席科学家

Vice-Chairman, Xu Xiping
Chairman of the Board & Chief Scientist of Shenzhen AUSA Pharmaceuticals Ltd.

副主任委员　杨大俊

亚盛医药董事长兼CEO

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

副主任委员　俞德超

信达生物制药（苏州）有限公司
董事长兼总裁

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

副主任委员　陈 力

华领医药技术（上海）有限公司
创始人、董事长、首席执行官

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

副主任委员　江宁军

基石药业（苏州）有限公司董事长兼
首席执行官

Vice-Chairman, Jiang Ningjun
Chairman of the Board & CEO of CStone Pharmaceuticals Co., Ltd.

第二届药物临床研究专业委员会

The 2nd Clinical Research Specialty Committee

名誉主任委员　孙 燕

中国工程院院士
中国医学科学院肿瘤医院国家新药临床研究中心主任

Honorary Chairman, Sun Yan
Academician of the Chinese Academy of Engineering
Director of National New Drugs Clinical Research Center, Cancer Hospital, Chinese Academy of Medical Sciences

名誉主任委员　葛均波

中国科学院院士
复旦大学生物医学研究院院长、复旦大学附属中山医院心内科主任

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

主任委员　霍 勇

北京大学第一医院心内科及心脏中心主任

Chairman, Huo Yong
Director of Cardiology and Heart Center, Peking University First Hospital

副主任委员　王拥军

首都医科大学附属北京天坛医院常务副院长

Vice-Chairman, Wang Yongjun
Executive Deputy Dean of Beijing Tian Tan Hospital, Capital Medical University

副主任委员　季加孚

北京大学肿瘤医院院长

Vice-Chairman, Ji Jiafu
President of Beijing Cancer Hospital

副主任委员　石远凯

国家癌症中心副主任、中国医学科学院肿瘤医院副院长

Vice-Chairman, Shi Yuankai
Deputy Director of National Cancer Centre
Vice President of Cancer Hospital, Chinese Academy of Medical Sciences

副主任委员　侯 健

上海交通大学医学院附属仁济医院血液内科主任

Vice-Chairman, Hou Jian
Director of Department of Hematology, Renji Hospital, Shanghai Jiaotong University School of Medicine

副主任委员　王广发

北京大学第一医院呼吸科主任

Vice-Chairman, Wang Guangfa
Director of Department of Respiration, Peking University First Hospital

副主任委员　崔一民

北京大学第一医院临床试验中心主任

Vice-Chairman, Cui Yimin
Director of Clinical Trial Center, Peking University First Hospital

副主任委员　李文斌

首都医科大学附属北京天坛医院神经肿瘤综合科主任

Vice-Chairman, Li Wenbin
Director of Comprehensive Treatment Ward of Neuro-Oncology, Beijing Tian Tan Hospital, Capital Medical University

副主任委员　张抒扬

中国医学科学院北京协和医院
党委书记、副院长

Vice-Chairman, Zhang Shuyang
Secretary of the Party & Vice President, Chinese Academy of Medical Sciences & Peking Union Medical College Hospital

副主任委员　秦叔逵

解放军东部战区总医院全军肿瘤中心主任

Vice-Chairman, Qin Shukui
Director of PLA Cancer Center

副主任委员　吴一龙

广东省人民医院终身教授主任

Vice-Chairman, Wu Yilong
Tenured Professor, Director of Guangdong General Hospital

第二届医药政策专业委员会

The 2nd Medicinal Policy Specialty Committee

主任委员　邵　蓉

中国药科大学教授、国家药物政策与医药产业经济研究中心执行副主任

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

副主任委员　史录文

北京大学药学院药事管理与临床药学系主任

Vice-Chairman, Shi Luwen
Director of Department of Pharmacy Administration and Clinical Pharmacy, School of Pharmaceutical Sciences, Peking University

副主任委员　朱恒鹏

中国社会科学院经济研究所副所长

Vice-Chairman, Zhu Hengpeng
Deputy Director of Institute of Economics, Chinese Academy of Social Sciences

副主任委员　胡　欣

北京医院药学部主任

Vice-Chairman, Hu Xin
Director of Department of Pharmacy, Beijing Hospital

副主任委员　刘军帅

山东省青岛市社会保险研究会副会长

Vice-Chairman, Liu Junshuai
Vice-President of Qingdao Social Insurance and Research Association

副主任委员　陈　川

北京华康管理咨询有限公司董事长

Vice-Chairman, Chen Chuan
Chairman of Beijing HuaKang Healthcare Consulting Co., Ltd.

副主任委员　武志昂

沈阳药科大学工商管理学院教授

Vice-Chairman, Wu Zhi'ang
Professor of School of Business Management, Shenyang Pharmaceutical University

副主任委员　陈　文

复旦大学公共卫生学院院长

Vice-Chairman, Chen Wen
Dean of School of Public Health, Fudan University

副主任委员　王 波

北京秦脉医药咨询有限责任公司
董事长

Vice-Chairman, Wang Bo
Chairman of Beijing ChnMed Pharmaceutical Technology Development Co., Ltd.

副主任委员　冯 毅

四川科伦药业股份有限公司研发
副总裁兼首席战略官

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

副主任委员　宣建伟

中山大学医药经济研究所所长

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

第二届医药创新投资专业委员会

The 2nd Pharmaceutical Innovation Investment Specialty Committee

主任委员　田 源

元明资本创始合伙人

Chairman, Tian Yuan
Founding Partner of Yuanming Capital

副主任委员　杜 莹

再鼎医药董事长兼首席执行官

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

副主任委员　李凯军

醴泽资本管理合伙人

Vice-Chairman, Li Kaijun
Managing Partner of LYZZ Capital

副主任委员　朱晋桥

倚锋资本董事长

Vice-Chairman, Zhu Jinqiao
Chairman of EFung Capital

副主任委员　陈鹏辉

博远资本创始合伙人

Vice-Chairman, Chen Penghui
Founding Partner of Biotrack Capital

副主任委员　梁颖宇

启明创投主管合伙人

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

副主任委员　易诺青

高瓴资本集团合伙人

Vice-Chairman, Yi Nuoqing
Partner of Hillhouse Capital Management, Ltd.

副主任委员　储慧斌

海捷投资控股集团首席合伙人

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

副主任委员　蔡达建

高特佳投资集团创始人、董事长

Vice-Chairman, Cai Dajian
Founder & Chairman of GTJA Investment Group

副主任委员　陆潇波

红杉资本中国基金医疗合伙人

Vice-Chairman, Lu Xiaobo
Partner of Sequoia Capital China

副主任委员　余世新

招商局集团健康产业事业部部长

Vice-Chairman, Yu Shixin
General Manager of Healthcare & Pharmaceutical Industry Development, China Merchants Group Limited

第一届创新研发服务专业委员会

The 1st Innovation R&D Services Specialty Committee

主任委员　谭凌实

缔脉生物医药科技（上海）有限公司
董事长兼首席执行官

Chairman, Tan Lingshi
Chairman of the Board & CEO, dMed Biopharmaceutical Co., Ltd.

副主任委员　张 丹

方恩医药发展有限公司董事长

Vice-Chairman, Zhang Dan
Chairman of the Board, Fountain Medical Co., Ltd.

副主任委员　洪 浩

凯莱英医药集团（天津）股份
有限公司董事长兼CEO

Vice-Chairman, Hong Hao
Chairman of the Board & CEO, Asymchem Laboratories (Tianjin) Co., Ltd.

副主任委员　闻丹忆

上海立迪生物技术股份有限公司
董事长

Vice-Chairman, Wen Danyi
Chairman of the Board, Shanghai LIDE Biotech Co., Ltd.

医药企业合规专业委员会发起人

Sponsors of Ethics and Business Compliance Specialty Committee

宋瑞霖 Song Ruilin	中国医药创新促进会会长 Chairman, China Pharmaceutical Innovation and Research Development Association
邵 蓉 Shao Rong	中国药科大学教授、国家药物政策与医药产业经济研究中心执行副主任 Professor, Vice Executive Director of the Research Center of National Drug Policy & Ecosystem of China Pharmaceutical University
史录文 Shi Luwen	北京大学药学院药事管理与临床药学系主任 Director of Department of Pharmacy Administration and Clinical Pharmacy, School of Pharmaceutical Sciences, Peking University
宋华琳 Song Hualin	南开大学法学院副院长 Associate Dean of School of Law, Nankai University
刘 鹏 Liu Peng	中国人民大学公共管理学院行政管理学系副教授 Associate Professor of School of Public Administration and Policy, Renmin University of China

心血管药物临床研究专业委员会发起人

Sponsors of Clinical Research on Cardiovascular Drugs Specialty Committee

霍 勇 Huo Yong	北京大学第一医院心内科及心脏中心主任 Director of Cardiology and Heart Center, Peking University First Hospital
葛均波 Ge Junbo	中国科学院院士、上海复旦大学附属中山医院心内科主任 Academician of Chinese Academy of Sciences Dean of Institutes of Biomedical Sciences of Fudan University, Director of Cardiology Department, Zhongshan Hospital Fudan University
张抒扬 Zhang Shuyang	北京协和医院党委书记、副院长 Secretary of the Party & Vice President, Chinese Academy of Medical Sciences & Peking Union Medical College Hospital
陈纪言 Chen Jiyan	广东省人民医院心内科主任 Director of Department of Cardiology, Guangdong Provincial People's Hospital
袁祖贻 Yuan Zuyi	西安交通大学医学院第一附属医院心内科主任 Director of Cardiology Department, the First Affiliated Hospital of Xi'an Jiaotong University

脑神经药物临床研究专业委员会发起人

Sponsors of Clinical Research on Cranial Nerve Drugs Specialty Committee

王拥军 Wang Yongjun	首都医科大学附属北京天坛医院常务副院长 Executive Deputy Dean of Beijing Tian Tan Hospital, Capital Medical University
张亚卓 Zhang Yazhuo	北京神外研究所所长 Director of Beijing Neurosurgical Institute
王伊龙 Wang Yilong	首都医科大学附属北京天坛医院院长助理兼神经病学中心副主任 Assistant of Dean & Vice Director, Neurosurgery Center Beijing Tiantan Hospital, Capital Medical University
石 进 Shi Jin	中国人民解放军空军总医院神经内科主任 Director of Neurology Department of Air Force General Hospital, PLA
李文斌 Li Wenbin	首都医科大学附属北京天坛医院神经肿瘤综合科主任 Director of Comprehensive Treatment Ward of Neuro-Oncology, Beijing Tian Tan Hospital, Capital Medical University

抗肿瘤药物临床研究专业委员会发起人

Sponsors of Clinical Research on Oncology Drugs Specialty Committee

秦叔逵 Qin Shukui	解放军东部战区总医院全军肿瘤中心主任 Director of PLA Cancer Center
石远凯 Shi Yuankai	国家癌症中心副主任、中国医学科学院肿瘤医院副院长 Vice President, Cancer Hospital, Chinese Academy of Medical Sciences & Peking Union Medical College
吴一龙 Wu Yilong	广东省人民医院终身教授主任 Tenured Professor, Director of Guangdong General Hospital
侯 健 Hou Jian	上海交通大学医学院附属仁济医院血液内科主任 Director of Department of Hematology, Renji Hospital, Shanghai Changzheng Jiaotong University School of Medicine
李 进 Li Jin	上海同济大学附属东方医院肿瘤医学部主任 Director of Department of Oncology, Tongji University Shanghai East Hospital
梁 军 Liang Jun	北京大学国际医院副院长、肿瘤中心主任、药物临床试验机构主任 Vice President, Director of Department of Oncology, Director of Clinical Trials Center, Peking University International Hospital

重要活动 | Important Events

中国药促会2019年会长会议扩大会议（2019年1月12日•烟台）

2019 PhIRDA President Board Meeting (January 12, 2019, Yantai)

刘殿波会长、宋瑞霖执行会长、蒋华良副会长、丁列明副会长、柯尊洪副会长、舒畅副会长、临床专委会霍勇主委、临床专委会张抒扬副主委、医药政策专委会邵蓉主委、研发专委会王印祥主委、冯岚秘书长等出席会议，与会代表围绕第十一届组织机构调整、章程/会费标准修订以及拆分临床研究专业委员会等问题进行了讨论并达成共识。

The meeting was attended by Chairman Liu Dianbo, Executive President Song Ruilin, Vice President Jiang Hualiang, Vice President Ding Lieming, Vice President Ke Zunhong, Vice President Shu Chang, Chairman of Clinical Research Specialty Committee Huo Yong, Vice Chairman Zhang Shuyang, Chairman of Medicinal Policy Specialty Committee Shao Rong, Chairman of Drug R&D Specialty Committee Wang Yinxiang, and Secretary-General Feng Lan etc. After discussion, participants reached a consensus on the adjustment of organization structure of the 11th PhIRDA General Assembly, modification of the Constitution of PhIRDA / membership fee standards, and restructure of the Clinical Research Specialty Committee.

参会代表合影

Photograph of Representatives

第十一届会员大会（2019年9月20日•苏州）

11th PhIRDA General Assembly (September 20, 2019, Suzhou)

参会代表合影
Photograph of Representatives

会场全景
Plenary Meeting

宋瑞霖执行会长作工作报告
Mr. Song Ruilin, PhIRDA Executive President, delivered a work report

新任监事代表蒋华良院士发言
Dr. Jiang Hualiang, Supervisor Representative of PhIRDA, made a speech

冯岚秘书长主持会议
Ms. Feng Lan, PhIRDA Secretary-General, chaired the meeting

国务院国资委刘续浩二级巡视员讲话
Mr. Liu Xuhao, Counsel of Bureau of Party Building Affairs for Industry Associations and Chambers of Commerce of the State-owned Assets Supervision and Administration Commission of the State Council (SASAC), addressed a speech

第十一届理事会第一次会议（2019年9月20日•苏州）

The First Meeting of 11th PhIRDA Board of Directors (September 20, 2019, Suzhou)

中国药促会会长宋瑞霖发表当选感言并作工作建议

Mr. Song Ruilin was elected as Chairman of PhIRDA and proposed work plan

参会代表合影

Photograph of Representatives

中国罕见病联盟成立大会（2018年10月24日•北京）

Inaugurating Meeting for China Alliance for Rare Diseases (October 24, 2018, Beijing)

由中国药促会会同北京协和医院、中国医院协会和中国研究型医院学会共同发起的中国罕见病联盟，在北京召开了成立大会。中国科学院院士、北京协和医院院长赵玉沛和国家卫健委医政医管局局长张宗久以及来自医院、患者组织、医药企业等各界专家、学者共400多人参加会议。与会专家就罕见病研究进展、药物研发等进行学术交流，通过了联盟第一届理事长、副理事长和秘书长名单，并举行了《中国第一批罕见病目录释义》的新书首发仪式。

China Alliance for Rare Diseases (CARD), initiated by PhIRDA, Peking Union Medical College Hospital (PUMCH), Chinese Hospital Association (CHA) and Chinese Research Hospital Association (CRHA), held its inaugurating meeting in Beijing. The meeting was attended by Zhao Yupei, Academician of the Chinese Academy of Sciences, President of Peking Union Medical College Hospital, Zhang Zongjiu, Director-General of Bureau of Medical Administration, National Health Commission, as well as experts and scholars from hospitals, patient organizations and pharmaceutical enterprises. The experts attending the meeting had academic exchanges on the research progress of rare diseases and drug R&D. The meeting elected Chairman, Vice Chairman and Secretary-General of CARD. The book *Compendium of China's First List of Rare Diseases* also make its debut release on the meeting.

2019国际创新临床研究大会（2019年6月27日•杭州）

2019 International Innovative Clinical Research Conference (June 27, 2019, Hangzhou)

中国药促会、中国心血管健康联盟、中国抗血栓药物治疗联盟、杭州市投资促进局、杭州钱塘新区管委会、美国华裔血液及肿瘤专家学会（CAHON）联合主办的“2019国际创新临床研究大会”在杭州召开。大会围绕创新药物与细胞疗法国际多中心临床研究的开展以及大数据在指导临床研究与应用等领域的热点前沿问题设置主题报告和专题讨论环节，吸引了国内外知名临床专家、临床研究机构资深研究人员以及医药企业科研人员在内的共计300余人共聚一堂。

会议期间，中国药促会与《新英格兰医学杂志》共同签署了战略合作协议。双方希望通过加深合作、充分调动自身资源，共同促进中国本土的临床试验能力提升，为加快我国临床研究水平尽早与国际水平接轨贡献力量。

The 2019 International Innovative Clinical Research Conference, co-hosted by PhIRDA, Chinese Cardiovascular Association (CCA), China Antithrombotic Pharmacotherapy Alliance (ChinaAPA), Hangzhou Investment Promotion Bureau, Administrative Committee of Hangzhou Qiantang New Area, Chinese American Hematologist and Oncologist Network (CAHON), was successfully held in Hangzhou. The conference established various keynote speeches and panels themed on the International Multi-center Clinical Trial (IMCT) for innovative drugs and cell therapy, the role of big data in guiding clinical research and application, as well as other hotspots and frontier issues, which gathered domestic and foreign well-known clinical experts, senior investigators from clinical institutions, scientific researchers from pharmaceutical companies, a total of over 300 people attendees.

During the meeting, PhIRDA and *New England Journal of Medicine* (*NEJM*)signed a strategic cooperation agreement. The both sides were dedicated to promoting the capacity of domestic clinical research by deepening mutual cooperation and giving full play to their own resources, so as to gain momentum for ranging China’s clinical research into an international level.

第十届中国医院药学政策论坛（2019年7月19日·哈尔滨）

The 10th China Hospital Pharmacy Policy Forum (July 19, 2019, Harbin)

由中国药促会、中国药师协会和中国医院协会共同主办的第十届中国医院药学政策论坛在哈尔滨召开。在药学论坛创办十周年之际，来自全国各地三甲医院院长、药剂科主任、医保部门负责人及地方医保经办机构相关领导、知名医药企业代表约400余人共聚一堂，围绕深化医改新形势下药师价值及药学服务内涵进行了热烈探讨，并对近期与药师工作相关的热点政策及产业趋势等进行了深入交流。

The 10th China Hospital Pharmacy Policy Forum, co-hosted by PhIRDA, Chinese Pharmacists Association and Chinese Hospital Association (CHA) was successfully held in Harbin. On the occasion of the 10th anniversary, China Hospital Pharmacy Policy Forum gathered over 400 attendees including presidents from Class-A hospitals across the country, directors of pharmacy departments, persons in charge for healthcare security, local medical insurance leaders and representatives from well-known pharmaceutical companies. The attendees made a lively discussion on topics including the value of pharmacists and significance of pharmacy service under the health reform deepening, and exchanged opinions on recent policies on pharmacists, as well as industry trends etc.

2019“独墅湖杯”医药创新品牌评选系列活动

2019 ‘Dushu Lake Prize’ Selection Activities of China Pharmaceutical Innovation Brand

陈凯先院士、丁健院士、蒋华良院士、岳建民院士、王军志院士、来茂德教授、石远凯教授、吴晓明教授、吴春福教授、宋瑞霖会长、陈晓光研究员、李佳研究员、马军教授等专家出席复审会议（2019年7月3日·北京）

The Review Meeting was attended by Academician Chen Kaixian, Academician Ding Jian, Academician Jiang Hualiang, Academician Yue Jianmin, Academician Wang Junzhi, Professor Lai Maode, Professor Shi Yuankai, Professor Wu Xiaoming, Professor Wu Chunfu, Chairman Song Ruilin, Researcher Chen Xiaoguang, Researcher Li Jia, Professor Ma Jun. (July 3, 2019, Beijing)

陈凯先院士、赵凯院士、丁健院士、葛均波院士、蒋华良院士、岳建民院士、王军志院士、石远凯教授、吴晓明教授、吴春福教授、宋瑞霖会长等专家出席终审会议（2019年9月21日·苏州）

The Final Review Meeting was attended by Academician Chen Kaixian, Academician Zhao Kai, Academician Ding Jian, Academician Ge Junbo, Academician Jiang Hualiang, Academician Yue Jianmin, Academician Wang Junzhi, Professor Shi Yuankai, Professor Wu Xiaoming, Professor Wu Chunfu, Chairman Song Ruilin and other experts. (September 21, 2019, Suzhou)

领导、颁奖嘉宾与获奖者合影（2019年9月21日·苏州）
Winners, Award Announcers and Presenters, Host Representatives and VIP Guests (September 21, 2019 Suzhou)

“医药创新终身成就奖”获奖者孙燕院士（左二）与陈凯先院士（右二）、吴庆文书记（左一）、石远凯副院长（右一）合影（2019年9月21日·苏州）
Winner of Lifetime Achievement Award of China Pharmaceutical Innovation:
Academician Sun Yan (the second from left)
Award Announcers and Presenters:
Academician Chen Kaixian (the second from right);
Secretary Wu Qingwen (the first from left);
Vice President Shi Yuankai (the first from right)
(September 21, 2019 Suzhou)

“独墅湖杯”医药创新品牌评选获奖名单

Award Winners for “Dushu Lake Prize” Selection Activities of China Pharmaceutical Innovation Brand

医药创新终身成就奖

Lifetime Achievement Award of China Pharmaceutical Innovation

孙　燕 Sun Yan	中国工程院院士 中国医学科学院肿瘤医院国家新药临床研究中心名誉主任 Academician of the Chinese Academy of Engineering, Director of National New Drugs Clinical Research Center, Cancer Hospital,Chinese Academy of Medical Sciences

最具影响力药物研发领军人物（海外华人奖）

Most Innovative Figure of Drug R&D Award (International Areas)

刘勇军 Liu Yongjun	赛诺菲集团全球研究部总裁 Global Head of Research, Sanofi

最具影响力药物研发领军人物

Winner of Most Innovative Figure of Drug R&D Award

俞德超 Yu Dechao	信达生物制药（苏州）有限公司董事长兼总裁 Chairman of the Board & President, Innovent Biologics (Suzhou) Co., Ltd.

最具影响力药物临床研究领军人物

Winners of Most Innovative Figure of Clinical R&D Award

侯　健 Hou Jian	上海交通大学医学院附属仁济医院血液内科主任 Director of the Department of Hematology, Renji Hospital, Shanghai Jiao Tong University School of Medicine
张　力 Zhang Li	中国医学科学院北京协和医院教授 Professor of Department of Respiratory Medicine, Peking Union Medical College Hospital, Chinese Academy of Medical Sciences.

最具价值药物临床试验方案设计

Award for Clinical Trial Protocol Design

《鼻咽癌的吉西他滨联合顺铂诱导化疗》试验方案
方案主要设计者　中山大学肿瘤防治中心马骏教授
‘Gemcitabine and Cisplatin induction chemotherapy in nasopharyngeal carcinoma’ Clinical Trial Protocol
Principal Investigator: Ma Jun, Professor of Sun Yat-Sen University Cancer Center

最具临床价值创新药

Winner of Innovative Drug with Most Clinical Value Award

罗沙司他胶囊（爱瑞卓）　珐博进（中国）医药技术开发有限公司
Roxadustat Capsule from FibroGen (China) Medical Technology Development Co., Ltd.

最具临床价值儿童新药

Award for Innovative Pediatric Drug with Most Clinical Value

Sabin株脊髓灰质炎灭活疫苗（Vero细胞）；口服I型III型脊髓灰质炎减毒活疫苗（人二倍体细胞）
中国生物技术股份有限公司
Inactivated Poliomyelitis Vaccine Made From Sabin Strains (Vero cell) and Poliomyelitis (Live) Vaccine Type I Type III (Human Diploid Cell), Oral from China National Biotech Group

“最具影响力药物研发领军人物--海外华人奖”获奖者刘勇军（正中）与颁奖嘉宾丁健院士（右）、揭奖嘉宾宋文儒（左）合影
Winner of Most Innovative Figure of Drug R&D Award (International Areas):
Dr. Liu Yongjun (middle)
Award Announcers and Presenters:
Academician Ding Jian (right); Dr. Song Wenru (left)

“最具影响力药物研发领军人物”获奖者俞德超（正中）与颁奖嘉宾蒋华良院士（右）、揭奖嘉宾何如意（左）合影
Winner of Most Innovative Figure of Drug R&D Award:
Dr. Yu Dechao (middle)
Award Announcers and Presenters:
Academician Jiang Hualiang (right); Dr. He Ruyi (left)

“最具影响力药物临床研究领军人物”获奖者侯健（左三）、张力（右三）与颁奖嘉宾岳建民院士（右二）、吴晓明（左一），揭奖嘉宾吴春福（右一）、李文斌（左二）合影
Winners of Most Innovative Figure of Clinical R&D Award:
Prof. Hou Jian (the third from the left) and Prof. Zhang Li (the third from the right)
Award Announcers and Presenters:
Academician Yue Jianmin (the second from the right); Prof. Wu Xiaoming (the first from the left); Prof. Wu Chunfu (the first from the right); Dr. Li Wenbin (the second from the left)

“最具价值药物临床实验方案”获奖方案主要设计者马骏（正中）与颁奖嘉宾葛均波院士（右）、揭奖嘉宾张树才（左）合影
Winner of Clinical Trial Protocol Design Award:
Prof. Ma Jun (middle)
Award Announcers and Presenters:
Academician Ge Junbo (right); Dr. Zhang Shucai (left)

“最具临床价值创新药”获奖代表钟黎蕴华（右二）与颁奖嘉宾宣建伟（左二），揭奖嘉宾沈心亮（右一）、钟武（左一）合影
Winner of Innovative Drug with Most Clinical Value Award:
Ms. Zhongli Yunhua (the second from the right)
Award Announcers and Presenters:
Dr. Xuan Jianwei (the second from the left);
Prof. Shen Xinliang (the first from the right);
Dr. Zhong Wu (the first from the left)

“最具临床价值儿童新药”获奖代表杨晓明（正中）与颁奖嘉宾赵铠院士（右）、揭奖嘉宾任进（左）合影
Winner of Innovative Pediatric Drug with Most Clinical Value Award:
Mr. Yang Xiaoming (middle)
Award Announcers and Presenters:
Academician Zhao Kai (right)
Dr. Ren Jin (left)

第四届中国医药创新与投资大会（2019年9月21日-23日•苏州）

2019 China BioMed Innovation and Investment Conference (September 21-23, 2019, Suzhou)

由中国药促会联合中国医疗器械行业协会、中国医院协会、香港交易所和蓝迪国际智库共同主办的第四届中国医药创新与投资大会在苏州工业园区召开。

大会设置了包括临床数据首发、上市/非上市公司路演、医疗器械项目路演、国际路演、大数据+智慧医疗专场、AI+生物医药专场、罕见病专场、投资人经验分享论坛、跨境并购论坛、科创板论坛、上市服务机构专场、创新研发服务专场及香港交易所与创新企业闭门座谈会在内逾22场特色活动。

Co-hosted by PhIRDA, CAMDI, CHA, HKEX, and RDI, 2019 China BioMed Innovation and Investment Conference was held successfully in Suzhou Industrial Park.

Over 22 featured events, including Clinical-Trial Data Release of Innovative Drugs, Listed/Non-Listed Company Roadshow, Medical Devices Roadshow, International Roadshows, WIT-MED + Big Data Roadshow, Artificial Intelligence (AI) + BioMed Roadshow, Rare Diseases and Orphan Drugs Roadshow, Investors' Experience Sharing Forum, Cross Border M&A Forum, SSE STAR Market Forum, Service Agencies Roadshow, Service Company Roadshow, HKEX & Innovative Pharmaceutical Companies Forum and so on.

大会作为国内行业瞩目并具有广泛国际影响力的医药创新与投资界盛会，在成功举办前三届大会的基础上，继续坚持“推动国内外社会资本与医药创新结合，提高我国医药产业创新能力”的宗旨，深入解读中国医药创新和投融资政策，充分展示国内外医药创新成果和投资最新动向，为国内外医药创新项目、企业、投资人和资本搭建更加广泛、权威、多元的高端合作交流平台。

大会组委会收到来自国内外共180多个在研新药、医疗器械项目及相关公司路演项目申请，经过精心筛选最终有138个项目在大会上进行了现场展示；国家医药监管有关部门领导、国内外院士、国内外医药创新企业、研究院所及投资等领域700余家机构、3000余位行业人士莅临大会。

As an annual event with extensive international influence in pharmaceutical innovation and investment community, under the principle of ‘promoting the linkage between social capital and pharmaceutical innovation, and improving the innovation capability of pharmaceutical industry’, CBIIC makes in-depth interpretation on Chinese medical and pharmaceutical innovation, investment and financing policies and the latest trends on pharmaceutical innovation and investment at home and abroad, providing a high-end cooperation and exchange platform for domestic and foreign pharmaceutical innovation projects, enterprises, investors and capitals.

2019 CBIIC committee received more than 180 roadshow applications of new drugs and medical devices from home and abroad. After strict screening, 138 projects were finally presented at the conference. The conference was attended by leaders from departments of national medical supervision, academicians at home and abroad, over 700 institutions including global medical and pharmaceutical innovation enterprises, research institutes, investment institutions, and over than 3,000 industrial attendees.

大会开幕式主持人及致辞嘉宾

Moderators and Keynote Speakers at the Opening Ceremony

全国人大教科文卫委员会副主任委员、中国医院协会会长刘谦
Liu Qian, Vice-Chairman of Education, Science, Culture & Health Committee of the NPC, President of Chinese Hospital Association (CHA)

中国药促会会长宋瑞霖
Song Ruilin, Chairman of PhIRDA

苏州市人民政府副市长陆春云
Lu Chunyun, Vice Mayor of Suzhou People's Municipal Government

中国药促会2020-2021年度候任会长、先声药业董事长任晋生
Ren Jinsheng, 2020-2021 Annual Chairman-elect of PhIRDA, Chairman of Simcere Pharmaceutical Group

西湖大学副校长、复星医药首席科学顾问许田
Xu Tian, Vice President of Westlake University, Chief Scientific Advisor of Fosun Pharma

中国医疗器械行业协会常务副会长姜峰
Jiang Feng, Executive Vice President of China Association for Medical Devices Industry

多位重量级嘉宾现身大会开幕式，并做精彩报告

KOLs Delivered Inspiring Speeches at the Opening Ceremony

国家药品监督管理局政策法规司司长刘沛
新《药品管理法》对未来医药创新的影响
Liu Pei, Director-General of Department of Policies and Regulations, National Medical Products Administration (NMPA)
Impact of *New Pharmaceutical Administration Law* on the Future Development of Pharmaceutical Innovation

香港交易所集团行政总裁李小加
大医疗+大健康+大数据：近在眼前，还是远在天边?
Charles LI, Chief Executive of Hong Kong Exchanges and Clearing Limited (HKEX)
Big Medical + Big Healthcare + Big Data: Around the Corner, or Nowhere Near?

赛诺菲集团全球研究部总裁刘勇军
从免疫生物学转化为医学
Liu Yongjun, Global Head of Research, Sanofi
Translating Human Immunobiology to Life Changing Medicine

摩根大通医疗健康投资银行董事总经理 John Whittaker
全球资本市场医疗健康行业趋势展望
John Whittaker, Managing Director, J.P. Morgan Healthcare Investment Banking
Healthcare in Global Markets

“新《药品管理法》实施推动医药创新发展”主题讨论
Panel: The Implementation of *New Pharmaceutical Administration Law* Promotes Pharmaceutical Innovation

“全球医药创新发展趋势”主题讨论
Panel: Global Trends on Pharmaceutical Innovation R&D

“全球创新融资平台与发展未来”主题讨论
Panel: The Development and Future of Global Innovation Financing Platform

香港交易所与创新企业闭门座谈会
HKEX & Innovative Pharmaceutical Companies Close-door Meeting

各分会场盛况

Parallel Sessions

开展政策研讨 积极建言献策

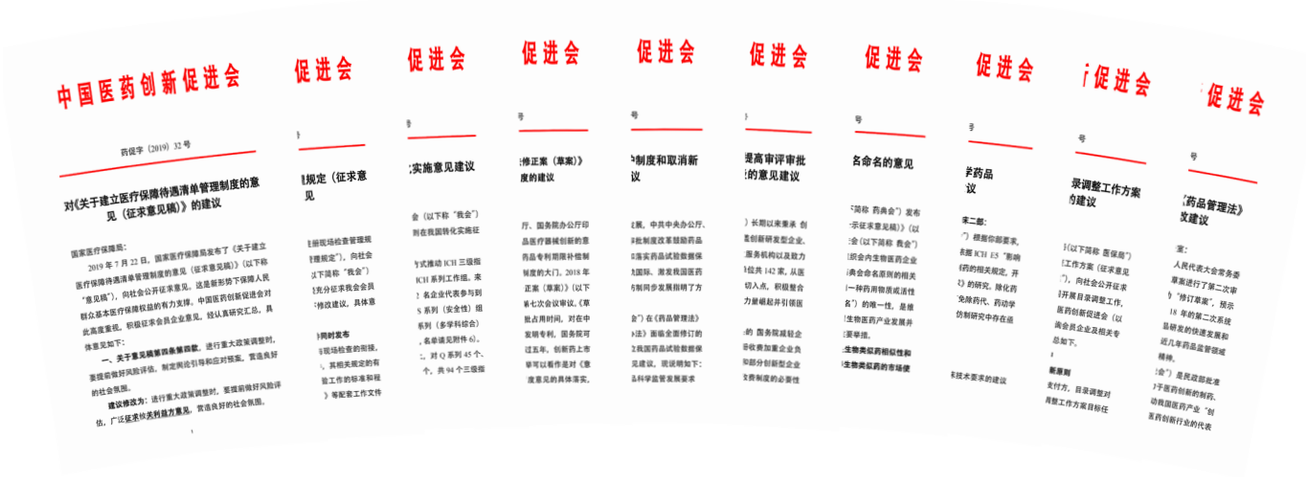
Making Discussions on Medical Policies & Providing Suggestions

2018-2019年度，中国药促会先后承接了国家医保局、国家药监局等部委及企业委托的政策研究课题十多项，并通过召开研讨会、组建研发联盟等方式不断寻求完善医药创新政策环境的方案，促进医药产业健康发展。

During 2018-2019, PhRIDA was commissioned by National Healthcare Security Administration (NHSA), National Medical Products Administration (NMPA) and other departments and enterprises to conduct over 10 research projects. By holding seminars and establishing alliances, PhIRDA keeps exploring strategies for seeking more optimized policy environment for pharmaceutical innovation and healthy development of pharmaceutical industry in China.

全国人民代表大会常务委员会法制工作委员会领导听取中国药促会对《中华人民共和国药品管理法（修订草案）》的相关意见和建议（2019年5月6日·北京）

Leaders from Legislative Affairs Commission of the Standing Committee of the National People's Congress (NPC) listened to PhIRDA's opinions and suggestions on the *Drug Administration Law* (*Amendment Draft*)(May 6, 2019, Beijing)



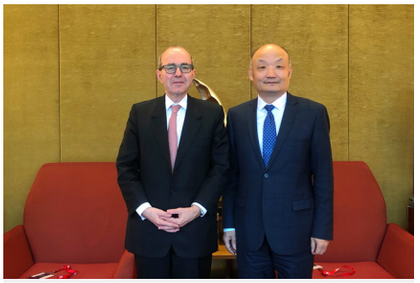
国际交流活动

International Cooperation and Exchanges

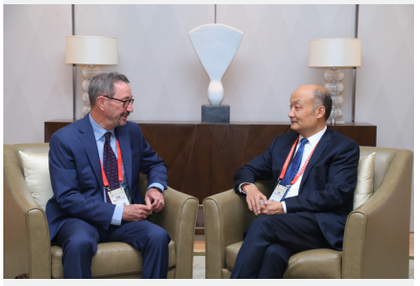
执行会长宋瑞霖出席第37届J.P. 摩根健康产业大会并作为讨论嘉宾参加亚洲论坛（2019年1月9日·美国旧金山）
PhIRDA Executive President Song Ruilin attended the 37th Annual J.P. Morgan Healthcare Conference and participated panel discussion in Asia Forum (January 9, 2019, San Francisco, USA)

执行会长宋瑞霖会见DIA全球首席执行官Barbara Lopez Kunz
（2019年5月22日·北京）
PhIRDA Executive President Song Ruilin met with Barbara Lopez Kunz, CEO of DIA Global (May 22, 2019, Beijing)

执行会长宋瑞霖会见荷兰王国卫生、福利和体育大臣Hugo de Jonge，荷兰王国卫生、福利和体育部长期护理司司长Cornelis van der Burg和国际合作司副司长Roland Driece等官员并参加高层午宴（2019年5月7日·北京）
PhIRDA Executive President Song Ruilin met with Hugo de Jonge, Minister of Health, Welfare and Sport in the Kingdom of the Netherlands, Cornelis van der Burg, Director of Long-Term Care Department of Ministry of Health, Welfare and Sport and Roland Driece, Deputy Director of the International Affairs Department and other officials, and attended the high-level luncheon (May 7, 2019, Beijing)



执行会长宋瑞霖会见国际药品制造商协会联合会（IFPMA）总干事Thomas Cueni（2019年3月26日·北京）
PhIRDA Executive President Song Ruilin met with IFPMA Director General Thomas Cueni (March 26, 2019, Beijing)



会长宋瑞霖会见加拿大驻上海总领事馆领事包孟德
（2019年9月23日·苏州）
PhIRDA Executive President Song Ruilin met with Douglas Bingeman, Consul & Trade Commissioner of Consulate General of Canada in Shanghai (September 23, 2019, Suzhou)

中国药促会代表团赴台参加“2018亚太生技投资论坛”和“2018台湾医疗科技展”（2018年11月28日-30日•中国台湾）

PhIRDA Delegation attended 2018 the Fifth Asia Pacific Biotech Investment Forum and 2018 Healthcare+ Expo Taiwan (November 28-30, 2018, Chinese Taiwan)

执行会长宋瑞霖围绕“大陆药物制度改革及医药产业的发展所面临的机遇与挑战”作主旨报告

PhIRDA Executive President Song Ruilin made a keynote speech on ‘The opportunities and challenges in the reform of the drug system and the development of the pharmaceutical industry in Chinese mainland’

中国药促会会员单位代表与会议嘉宾合影

Representatives of PhIRDA Members and conference attendees

中国药促会代表团赴日本参加“第八届亚洲制药组织合作会议”（2019年4月9日-10日•日本东京）

PhIRDA Delegation Attended 8th Asia Partnership Conference of Pharmaceutical Associations (APAC) (April 9-10, 2019, Tokyo, Japan)

APAC参会各国机构、组织代表合影
Photograph of the Representatives from APAC Members and Associations

中国药促会秘书长冯岚率团出席在日本东京召开的第八届亚洲制药组织合作会议（APAC），并与APAC药物开发联盟工作组及日本制药工业协会药物研发专业委员会召开座谈会。

PhIRDA delegation, led by Secretary-General Feng Lan attended the 8th Asia Partnership Conference of Pharmaceutical Associations (APAC) in Tokyo, Japan, holding seminars with APAC Drug Discovery Alliances Expert Working Group (DA-EWG) and R&D Committee of Japan Pharmaceutical Manufacturers Association (JPMA).

中国药促会代表团赴欧洲考察访问（2019年6月20日-25日•欧洲）

PhIRDA Delegation Visited Europe (June 20-25, 2019, Europe)

受荷兰驻华大使馆、荷兰创新中心和中德科教园邀请，中国药促会执行会长宋瑞霖率代表团拜访了荷兰和德国创新产业园区、医学研究中心、科研机构、大学院校和创新公司，并与中德科教园首席运营官Mike de Vries代表双方机构签署合作备忘录。

Invited by Embassy of the Kingdom of the Netherlands, Innovation Quarter and Sino German Hi-Tech Park, PhIRDA delegation, led by PhIRDA Executive President Song Ruilin, visited the innovation industrial parks, medical research centers, research institutes, universities and innovative companies in the Netherlands and Germany, and signed a memorandum of cooperation with Mike de Vries, COO of Sino German Hi-Tech Park, on behalf of the two parties.

中国药促会代表团与荷兰乌德勒支科技产业园会谈现场
Meeting with Utrecht Science Park Representatives

中国药促会代表团访问欧洲分子实验室
PhIRDA Delegation and Representatives from European Molecular Biology Laboratory (EMBL)

中国药促会代表访问海德堡大学附属医院
Meeting with Heidelberg University Hospital Representatives

中国药促会执行会长宋瑞霖与中德科教园首席运营官Mike de Vries代表双方机构签署合作备忘录
PhIRDA Executive President Song Ruilin signed a MOU with Mike de Vries, COO of Sino German Hi-Tech Park, on behalf of the two parties

中国药促会党组织建设

PhIRDA's Construction of Party Organization

中国药促会于2016年12月建立了中国工经联第十党支部。

积极开展组织学习，大力开展“不忘初心、牢记使命”主题教育活动，深入学习总书记重要讲话及相关精神，并努力与我会实际工作紧密结合，从社会组织工作层面推动党的事业全面发展。

The 10th Party branch of China Federation of Industrial Economics (CFIE) was established in December 2016.

PhIRDA actively organizes themed education on ‘remaining true to the original aspiration and keeping mission firmly in mind’ in Party organizations for studying General Secretary's important speeches and spirit, and it integrate it over PhIRDA’s work, to advance the cause of the Party in an all-round way from the social organizational level.

第十一届副会长
Vice Presidents of 11th General Assembly

任晋生 Ren Jinsheng	先声药业有限公司董事长 Chairman of the Board, Simcere Pharmaceutical Group
陈启宇 Chen Qiyu	上海复星医药（集团）股份有限公司执行董事、董事长 Executive Director, Chairman of the Board, Shanghai Fosun Pharmaceutical (Group) Co., Ltd.
孙飘扬 Sun Piaoyang	江苏恒瑞医药股份有限公司董事长 Chairman of the Board, Jiangsu Hengrui Medicine Co., Ltd.
丁列明 Ding Lieming	贝达药业股份有限公司董事长兼CEO Chairman of the Board & CEO, Betta Pharmaceutical Co., Ltd.
蒋建东 Jiang Jiandong	中国医学科学院药物研究所所长 Director, Institute of Materia Medica, Chinese Academy of Medical Sciences
刘殿波 Liu Dianbo	绿叶制药集团有限公司董事长 Chairman of the Board, Luye Pharma Group Co., Ltd.
柯尊洪 Ke Zunhong	成都康弘药业集团股份有限公司董事长 Chairman of the Board, Chengdu Kanghong Pharmaceutical Group Co., Ltd.
李　佳 Li Jia	中国科学院上海药物研究所所长 Director, Shanghai Institute of Materia Medica, Chinese Academy of Sciences.
闫凯境 Yan Kaijing	天士力医药集团股份有限公司董事长 Chairman of the Board, Tasly Pharmaceutical Group Co., Ltd.
赵　勇 Zhao Yong	上海医药集团股份有限公司党委副书记、副总裁 Deputy Secretary of the Party Committee & Vice President, Shanghai Pharmaceuticals Holding Co., Ltd.
张抒扬 Zhang Shuyang	中国医学科学院北京协和医院党委书记、副院长 Secretary of the Party & Vice President, Chinese Academy of Medical Sciences & Peking Union Medical College Hospital
李　燕 Li Yan	山东齐鲁制药集团有限公司总裁 President, Shandong Qilu Pharmaceutical Group Co., Ltd.
吴晓滨 Wu Xiaobin	百济神州中国区总经理兼总裁 General Manager of China & President, BeiGene Ltd.

第十一届理事
Directors of 11th General Assembly

刘革新 Liu Gexin	四川科伦药业股份有限公司董事长 Chairman of the Board, Sichuan Kelun Pharmaceutical Co., Ltd.
俞德超 Yu Dechao	信达生物制药（苏州）有限公司董事长兼总裁 Chairman of the Board & President, Innovent Biologics (Suzhou) Co., Ltd.
李　宁 Li Ning	上海君实生物医药科技股份有限公司总经理 General Manager, Shanghai Junshi Biosciences Co., Ltd.
叶宇翔 Ye Yuxiang	深圳信立泰药业股份有限公司董事、总经理 Director & General Manager, Shenzhen Salubris Pharmaceuticals Co., Ltd.
吕爱锋 Lv Aifeng	江苏豪森药业集团有限公司总裁 President, Jiangsu Hansoh Pharmaceutical Group Co., Ltd.
鲁先平 Lu Xianping	深圳微芯生物科技股份有限公司董事长、总裁 Chairman of the Board & President, Shenzhen Chipscreen Biosciences Co., Ltd.
杜　莹 Du Ying	再鼎医药董事长兼首席执行官 Chairman of the Board & CEO, ZAI Lab
刘世高 Liu Shigao	上海复宏汉霖生物技术股份有限公司总裁兼首席执行官 President & CEO, Shanghai Henlius Biotech, Inc.
吴劲梓 Wu Jinzi	歌礼生物科技（杭州）有限公司董事长 Chairman of the Board, Ascletis Bioscience Co., Ltd.
谢　东 Xie Dong	前沿生物药业（南京）股份有限公司董事长兼首席科学家 Chairman of the Board & CSO, Frontier Biotechnologies Inc.
陈保华 Chen Baohua	浙江华海药业股份有限公司总裁 President, Zhejiang Huahai Pharmaceutical Co., Ltd.
娄　竞 Lou Jing	三生制药集团董事长兼首席执行官 Chairman of the Board & CEO, 3S Pharmaceutical Group
薛　群 Xue Qun	北海康成制药有限公司创建人、董事长及首席执行官 Founder, Chairman of the Board & CEO, CANbridge Pharmaceuticals Inc.
李春波 Li Chunbo	浙江医药股份有限公司董事长 Chairman of the Board, Zhejiang Medicine Co., Ltd.

孔　泰 Kong Tai	北京泰德制药股份有限公司总裁 President, Beijing Tide Pharmaceutical Co., Ltd.
钟黎蕴华 Zhongli Yunhua	珐博进（中国）医药技术开发有限公司执行总裁 Managing Director, FibroGen (China) Medical Technology Development Co., Ltd.
王　勇 Wang Yong	南京圣和药业股份有限公司董事长 Chairman of the Board, Nanjing Sanhome Pharmaceutical Co., Ltd.
路孔明 Lu Kongming	中天（上海）生物科技有限公司董事长 Chairman of the Board, Microbio (Shanghai) Biotechnology Co., Ltd.
江宁军 Jiang Ningjun	基石药业（苏州）有限公司董事长兼首席执行官 Chairman of the Board & CEO, CStone Pharmaceuticals Co., Ltd.
陈　力 Chen Li	华领医药技术（上海）有限公司创始人、董事长、首席执行官 Founder, Chairman of the Board & CEO, Hua Medicine (Shanghai) Ltd.
杨大俊 Yang Dajun	亚盛医药董事长兼CEO Chairman of the Board & CEO, Ascentage Pharma
王印祥 Wang Yinxiang	北京加科思新药研发有限公司董事长兼首席执行官 Chairman of the Board & CEO, Jacobio Pharmaceuticals Co., Ltd.
崔昳聆 Cui Yiling	和记黄埔医药（上海）有限公司资深副总裁 Senior Vice President, Hutchison MediPharma Limited
易诺青 Yi Nuoqing	高瓴资本管理有限公司合伙人 Partner, Hillhouse Capital Management, Ltd.
陆潇波 Lu Xiaobo	红杉资本中国基金合伙人 Partner, Sequoia Capital China
田　源 Tian Yuan	元明资本创始合伙人 Founding Partner, YuanMing Capital
朱晋桥 Zhu Jinqiao	深圳市倚锋投资管理企业（有限合伙）董事长 Chairman of the Board, Shenzhen Efung Venture Capital Co., Ltd.
李凯军 Li Kaijun	上海醴泽投资管理有限公司管理合伙人 Managing Partner, LYZZ Capital
李　革 Li Ge	药明康德董事长兼首席执行官 Chairman of the Board & CEO, WuXi AppTec Co., Ltd.
张　丹 Zhang Dan	方恩（天津）医药发展有限公司董事长 Chairman of the Board, Fountain Medical (Tianjin) Co., Ltd.
吴晓明 Wu Xiaoming	中国药科大学原校长 Former President, China Pharmaceutical University
王拥军 Wang Yongjun	首都医科大学附属北京天坛医院常务副院长、党委副书记 Executive Deputy Dean & Deputy Secretary of the Party Committee, Beijing Tiantan Hospital, Capital Medical University

会员代表
Members & Representatives

王善春 Wang Shanchun	正大天晴药业集团股份有限公司总裁 President, Chia Tai Tianqing Pharmaceutical Group Co., Ltd.
李阳春 Li Yangchun	太极集团有限公司董事长 Chairman of the Board, Taiji Group Co., Ltd.
高任龙 Gao Renlong	华北制药集团有限责任公司副总经理 vice president, North China Pharmaceutical Group Corporation
周　凯 Zhou Kai	东北制药集团股份有限公司总经理 General Manager, Northeast Pharmaceutical Group Co., Ltd.
李安平 Li Anping	山西振东制药股份有限公司董事长 Chairman of the Board, Shanxi Zhendong Pharmaceutical Co., Ltd.
张成海 Zhang Chenghai	美罗药业股份有限公司董事长 Chairman of the Board, Merro Pharmaceutical Co., Ltd.
冯　毅 Feng Yi	华润双鹤药业股份有限公司董事长 Chairman of the Board, China Resources Double-Crane Pharmaceutical Co., Ltd.
郭殿武 Guo Dianwu	杭州民生药业有限公司首席科学家 Chief Scientist, Hangzhou Minsheng Pharmaceutical Co., Ltd.
汪　涛 Wang Tao	浙江佐力药业股份有限公司总经理 General Manager, Zhejiang Jolly Pharmaceutical Co., Ltd.
彭伟民 Peng Weimin	广西梧州中恒集团股份有限公司副总经理 vice president, Guangxi Wuzhou Zhongheng Group Co., Ltd.
于伟仕 Yu Weishi	悦康药业集团股份有限公司董事长 Chairman of the Board, Youcare Pharmaceutical Group Co., Ltd.

陈庆才
Chen Qingcai
江苏奥赛康药业股份有限公司董事长
Chairman of the Board, Jiangsu Aosaikang Pharmaceutical Co., Ltd.

王晓琳
Wang Xiaolin
重庆植恩药业有限公司副董事长
Vice Chairman, Zein Pharmaceutical Co., Ltd.

冯　鹤
Feng He
正大青春宝药业有限公司总裁
President, Chiatai Qingchunbao Pharmaceutical Co., Ltd.

徐希平
Xu Xiping
深圳奥萨医药有限公司董事长
Chairman of the Board, Shenzhen AUSA Pharmaceuticals Ltd.

任武贤
Ren Wuxian
亚宝药业集团股份有限公司董事长
Chairman of the Board, Yabao Pharmaceutical Group Co., Ltd.

葛啸虎
Ge Xiaohu
常州方圆制药有限公司董事长
Chairman of the Board, Changzhou Fangyuan Pharmaceutical Co., Ltd.

张海英
Zhang Haiying
青岛黄海制药有限责任公司董事长
Chairman of the Board, Qingdao Huanghai Pharmaceutical Co., Ltd.

张贵民
Zhang Guimin
鲁南制药集团股份有限公司董事长、总经理
Chairman of the Board & CEO, Lunan Pharmaceutical Group Co., Ltd.

萧　伟
Xiao Wei
江苏康缘药业股份有限公司董事长
Chairman of the Board, Jiangsu Kanion Pharmaceutical Co., Ltd.

孙　毅
Sun Yi
成都百裕制药股份有限公司董事长
Chairman of the Board, Chengdu Baiyu Pharmaceutical Co., Ltd.

杨代常
Yang Daichang
武汉禾元生物科技股份有限公司董事长
Chairman of the Board, Wuhan Healthgen Biotechnology Corp.

高　帆
Gao Fan
西藏易明西雅医药科技股份有限公司董事长
Chairman of the Board, Tibet Aim Pharm. Inc.

刘振腾
Liu Zhenteng
山东罗欣药业集团股份有限公司执行董事长
Executive Chairman of the Board, Luoxin Pharmaceutical 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.

张　洁
Zhang Jie
四川九章生物科技有限公司董事长
Chairman of the Board, Sichuan Jiuzhang Biological Science and Technology Co., Ltd.

廖昕晰
Liao Xinxi
博雅生物制药集团股份有限公司董事长
Chairman of the Board, Boya Bio-pharmaceutical Group Co., Ltd.

桑会庆
Sang Huiqing
上海仁会生物制药股份有限公司董事长
Chairman of the Board, Shanghai Benemae Pharmaceutical Co., Ltd.

李翰明
Li Hanming
广东天普生化医药股份有限公司首席执行官
CEO, Techpool Bio-Pharma 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兼总经理
Chairman of the Board & CEO, Amoy Diagnostics Co., Ltd.

王树彬
Wang Shubin
大连亚维药业有限公司董事长兼总经理
Chairman of the Board & General Manager, Dalian Asia Space Pharmaceutical Co., Ltd.

吕松涛
Lv Songtao
上海绿谷制药有限公司董事长
Chairman of the Board, Shanghai Green Valley Pharmaceutical Co., Ltd.

王　颖
Wang Ying
成都苑东生物制药股份有限公司董事长
Chairman of the Board, Chengdu Easton Biopharmaceuticals Co., Ltd.

李怡平
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上海药明巨诺生物科技有限公司首席执行官
CEO, JW Therapeutics (Shanghai) Co., Ltd.

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北京诺诚健华医药科技有限公司总经理
General Manager, Beijing InnoCare Pharma Tech Co., Ltd.

房健民
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荣昌生物制药（烟台）有限公司总经理兼首席科学官
General Manager & Chief Scientific Officer, RemeGen, Ltd.

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北京泛生子基因科技有限公司首席执行官
CEO, Genetron Health (Beijing) Co., Ltd.

赵　宏
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赛生医药江苏有限公司首席执行官兼总裁
CEO & President, SciClone Pharmaceuticals (Jiangsu) Co., Ltd.

周明东
Zhou Mingdong
上海泽生科技开发股份有限公司董事长、总经理
Chairman of the Board & CEO, Zensun (Shanghai) Sci & Tech Co., Ltd.

黄纯莹
Huang Chunying
东曜药业有限公司总经理
General Manager, TOT Biopharma Co., Ltd.

路　杨
Lu Yang
杭州阿诺生物医药科技有限公司首席执行官
CEO, Adlai Nortye Biopharma Co., Ltd.

梁文青
Liang Wenqing
长风药业股份有限公司首席执行官
CEO, CF Pharmtech, Inc.

高小明
Gao Xiaoming
合肥天麦生物科技发展有限公司董事长
Chairman of the Board, Hefei Tianmai Biotechnology Development Co., Ltd.

臧敬五
Zang Jingwu
天境生物科技（上海）有限公司首席执行官
CEO, I-Mab Biopharma Co., Ltd.

陈庚辉
Chen Genghui
北京文丰天济医药科技有限公司总经理
General Manager, Beijing Wen Feng Tianji Pharma Co., Ltd.

罗培志
Luo Peizhi
天演药业（苏州）有限公司董事长兼总裁
Chairman of the Board & President, Adagene (Suzhou) Limited.

储慧斌
Chu Huibin
海捷投资控股集团首席合伙人
Chief Partner, Hiyield Investment Holding Group

梁颖宇
Liang Yingyu
启明维创创业投资管理（上海）有限公司主管合伙人
Managing Partner, Qiming Weichuang Venture Capital Management (Shanghai) Co., Ltd.

胡雪峰
Hu Xuefeng
深圳市高特佳投资集团有限公司主管合伙人
Managing Partner, Shenzhen GTJA Investment Group Co., Ltd.

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

居伟民
Ju Weimin
中投海外直接投资有限责任公司总经理
President, CIC Capital Co., Ltd.

冀　文
Ji Wen
平安银行医疗健康文化旅游金融事业部总裁
President, Finance SBU of Healthcare Industries of Ping An Bank

陈　可
Chen Ke
博信股权投资基金管理股份有限公司总经理
General Manager, Boxin Fund Management Co.,Ltd.

陈鹏辉
Chen Penghui
博远资本创始合伙人
Founding Partner, Biotrack Capital

姚江涛
Yao Jiangtao
中航信托股份有限公司董事长
Chairman of the Board, AVIC Trust Co., Ltd.

王晓滨
Wang Xiaobin
宝石花医疗健康投资控股集团有限公司副董事长
Vice Chairman, Gem Flower Healthcare Investment Holding Group Co., Ltd.

周　浩
Zhou Hao
方圆基金管理（香港）有限公司合伙人
Partner, Prudence Investment Management (Hong Kong) Limited

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.

林　亮
Lin Liang
礼来亚洲基金合伙人
Partner, Lilly Asia Ventures

方　瑛
Fang Ying
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Founding Partner & CEO, Beijing Maplesea Capital Management Center

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鼎晖投资合伙人
Partner, CDH Investments

王　晖
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宁波弘晖股权投资合伙企业（有限合伙）管理及创始合伙人
Managing & Founding Partner, HighLight Capital

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交银国际（亚洲）有限公司总经理
General Manager, BOCOM International (Asia) Co., Ltd.

余世新
Yu Shixin
招商局海通贸易有限公司总经理
General Manager, China Merchants Hoi Tung Trading Co., Ltd.

周海冰
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北京大数长胜资产管理有限公司首席战略官
CSO, Beijing Great Numbers Asset Management Co., Ltd.

刘　浩
Liu Hao
浩悦资本有限公司创始人兼首席执行官
Founder & CEO, HaoYue Capital Ltd.

蔡大庆
Cai Daqing
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Founder & Managing Partner, Sherpa Venture Capital

曹彦凌
Cao Yanling
博裕投资顾问有限公司董事总经理
Managing Director, BOYU Capital Advisory Co., Ltd.

李　明
Li Ming
泰福资本管理合伙人
Managing Partner, TF Capital

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国泰君安证券股份有限公司产业研究院院长
Dean, Industry Research Institute, Guotai Junan Securities Co., Ltd.

张蕾娣
Zhang Leidi
国寿股权投资有限公司董事总经理
Managing Director, China Life Private Equity Investment Co., Ltd.

王闽川
Wang Minchuan
三正健康投资管理有限公司合伙人、董事总经理
Partner & Managing Director, 3H Health Investment Management Ltd.

郑效东
Zheng Xiaodong
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Chairman of the Board, Shanghai Tofflon Science and Technology Co., Ltd.

王锦刚
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北京科信必成医药科技发展有限公司总经理
General Manager, CoSci Med-Tech Co., Ltd.

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药渡经纬信息科技（北京）有限公司董事长
Chairman of the Board, Pharmacodia (Beijing) Co., Ltd.

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Tan Lingshi
缔脉生物医药科技（上海）有限公司董事长兼首席执行官
Chairman of the Board & CEO, dMed Biopharmaceutical Co., Ltd.

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

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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.

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General Manager, Zhejiang Jiuzhou Pharmaceutical Co., Ltd.

宋青春
Song Qingchun
北京春天医药科技发展有限公司总经理
General Manager, Proswell Medical Co., Ltd.

温书豪
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深圳晶泰科技有限公司董事长
Chairman of the Board, XtalPi Inc.

刘　川
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高思华
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Former President, Beijing University of Chinese Medicine

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中国药促会大事记（2018年10月–2019年9月）

2018年

10月24日 由中国药促会会同北京协和医院、中国医院协会和中国研究型医院学会共同发起的中国罕见病联盟，在北京召开了成立大会，并发布《中国第一批罕见病目录释义》。

10月27日 由中国药促会和贝达药业共同主办的"凯美纳成果发布七周年学术峰会"在北京举行。

11月7日 由中国药促会和国家卫健委国际交流与合作中心主办，复星国际承办的首届中国国际进口博览会"全球动力：共筑健康梦想"世界健康科技创新论坛在上海举行。

11月28日 中国药促会作为支持单位率团参加"2018亚太生技投资论坛"和"2018台湾医疗科技展"。

12月28日 中国药促会召开国家药监局委托课题"关于药品专利链接和专利期限补偿制度的研究"课题结题会在北京召开。

2019年

1月7日 中国药促会向发改委、财政部提出《关于完善药品注册收费制度提高审评审批效率促进医药产业转型升级的意见建议》。

1月9日 中国药促会执行会长宋瑞霖应邀出席在美国旧金山举行的第37届J.P.摩根健康产业大会，并作为主要嘉宾参与讨论。

1月12日 中国药促会在山东烟台召开了2019年会长会议扩大会议，并表决通过了鲁晓缇副秘书长的任命。

1月12日 北京文丰天济医药科技有限公司、天演药业（苏州）有限公司和大连亚维药业有限公司正式加入中国药促会。

1月22日 中国药促会携手L.E.K.合作完成的《保护创新、促进仿制——对中国建立药品专利保护体系的政策建议》成果在北京发布。

2月25日 由中国药促会联合中国科学院上海药物研究所召开两院院士座谈会，并向中央深改委提交"关于深刻认识和准确把握医药产业环境变化，化解医药创新发展系统性风险"报告。

3月23日 中国药促会执行会长宋瑞霖荣获百华协会"百华生物医药终身成就奖"。

3月26日 中国药促会执行会长宋瑞霖会见了国际药品制造商协会联合会（IFPMA）总干事Thomas Cueni。

4月9日-10日 中国药促会率团出席在日本东京召开的第八届亚洲制药组织合作会议（APAC）。

5月6日 全国人民代表大会常务委员会法制工作委员会领导走访中国药促会，召开座谈会听取中国药促会对《中华人民共和国药品管理法（修订草案）》的相关意见和建议。

5月18日-19日 中国药促会主办的"十二五"国家"重大新药创制专项"标志性成果研讨会暨朗沐上市五周年庆典在成都与北京双城召开。

5月28日-30日 中国药促会受港交所邀请组团赴港参加"第二届香港交易所生物科技周"活动。

6月17日 中国药促会党支部暨中国工业经济联合会第十党支部召开"不忘初心、牢记使命"主题教育动员部署会议。

6月20日-25日 中国药促会执行会长宋瑞霖率代表团拜访了荷兰和德国创新产业园区、医学研究中心、科研机构、大学院校和创新公司，并与中德科教园签署合作备忘录。

6月24日 成都苑东生物制药股份有限公司、深圳晶泰科技有限公司正式加入中国药促会。

6月27日 中国药促会会同中国心血管健康联盟等机构共同主办的"2019国际创新临床研究大会"在杭州召开。

6月27日 中国药促会与《新英格兰医学杂志》（NEJM）在杭州签署战略合作协议。

7月3日 2019"独墅湖杯"医药创新品牌评选复审会议在北京召开，会议评出各项目提名奖，并对社会公示。

7月15日 中国药促会与山东省人民政府签订医药创新发展合作协议。

7月18日 中国药促会在哈尔滨召开2019年度会员单位联络秘书工作会议。

7月19日 由中国药促会、中国药师协会和中国医院协会共同主办的第十届中国医院药学政策论坛在哈尔滨召开。

7月25日 中国药促会与深圳市坪山区人民政府签订合作协议，双方将共同推动中国医药创新、共建粤港澳大湾区生物医药创新高地。

9月20日 中国药促会第十一届会员大会在江苏省苏州市召开。

9月20日 北京科林利康医学研究有限公司、三正健康投资管理有限公司正式加入中国药促会。

9月20日 中国药促会第十一届理事会第一次会议在江苏省苏州市召开。宋瑞霖当选2019-2020年度会长。

9月21日 2019"独墅湖杯"医药创新品牌评选终审会议及颁奖典礼在苏州广播电视总台召开。

9月21日-23日 由中国药促会联合中国医疗器械行业协会、中国医院协会、香港交易所和蓝迪国际智库共同主办的第四届中国医药创新与投资大会在苏州工业园区召开。

9月23日 中国药促会会长宋瑞霖会见了加拿大驻上海总领事馆领事包孟德。

Remarkable Events of PhIRDA
(October, 2018 - September, 2019)

2018

October 24 — China Alliance for Rare Diseases (CARD), initiated by PhIRDA, Peking Union Medical College Hospital (PUMCH), Chinese Hospital Association (CHA) and Chinese Research Hospital Association (CRHA), held its inaugurating meeting in Beijing. The book *Compendium of China's First List of Rare Diseases* made its debut release on the meeting.

October 27 — PhIRDA and Beta Pharmaceuticals co-hosted the 7th Listing Anniversary Academic Summit of Conmana in Beijing.

November 7 — The World Healthcare Science Innovation Forum themed Global Momentum: Share Dream for Health, hosted by PhIRDA and International Health Exchange and Cooperation Center NHC PRC (IHECC), organized by Shanghai Fosun Pharmaceutical, was successfully held on the First China International Import Expo (CIIE) in Shanghai.

November 28 — PhIRDA Delegation attended '2018 the Fifth Asia Pacific Biotech Investment Forum' and '2018 Healthcare+ Expo Taiwan' as the supporter.

December 28 — The closing seminar 'Research on Drug Patent Linkage and Patent-term Compensation System' conducted by PhIRDA was held in Beijing.

2019

January 7 — PhIRDA submitted *Suggestions on Improving the Drug Registration Fee System and the Efficiency of Review and Approval to Promote the Transformation and Upgrading of the Pharmaceutical Industry* to National Development and Reform Commission (NDRC) and the Ministry of Finance.

January 9 — PhIRDA Executive President Song Ruilin was invited to attend the 37th Annual J.P. Morgan Healthcare Conference and participated panel discussion in Asia Forum.

January 12 — 2019 PhIRDA President Board Meeting was held in Yantai City, Shandong Province, and appointed Ms. Lu Xiaoti as Deputy Secretary-General of PhIRDA by voting.

January 12 — Beijing Wen Feng Tianji Pharma Co., Ltd., Adagene (Suzhou) Limited, and Dalian Asia Space Pharmaceutical Co., Ltd. officially joined PhIRDA.

January 22 — The report of *Innovation Driver and Generic Complements - Policy Recommendations for Drug Patent Protection in China* jointly completed by PhIRDA and L.E.K. were released in Beijing.

February 25 — PhIRDA and Shanghai Institute of Materia Medica of CAS jointly hosted the Symposium by Academicians of the Chinese Academy of Sciences and Chinese Academy of Engineering, and submitted the report *Deeply Understanding and Precisely Targeting Changes in Pharmaceutical Industry to Manage Risks of Pharmaceutical Innovation and Development* to Central Committee for Deepening Overall Reform.

March 23 — PhIRDA Executive President Song Ruilin was awarded 'BayHelix Lifetime Achievement Award' by the BayHelix Group.

March 26 — PhIRDA Executive President Song Ruilin met with International Federation of Pharmaceutical Manufacturers Associations (IFPMA) Director General Thomas Cueni.

April 9-10 — PhIRDA Delegation Attended 8th Asia Partnership Conference of Pharmaceutical Associations (APAC) in Tokyo, Japan.

May 6 — Leaders of the Administrative Law Office of the Legal Affairs Working Committee of the NPC Standing Committee visited PhIRDA and listened to comments on the *Drug Administration Law (Amendment Draft)* by holding a symposium.

May 18-19 — The seminar on the remarkable results of National science and technology Major Project for 'New Drugs Development' of the '12th Five-Year Plan' and the *5th anniversary celebration of Longmu (Conbercept)'s listing* were held in Chengdu and Beijing.

May 28-30 — Invited by HKEX, PhIRDA Delegation attended 'the Second HKEX Biotech Week' in Chinese Hong Kong.

June 17 — PhIRDA and 10th Party branch of China Federation of Industrial Economics (CFIE) held a themed education on *'Remaining True to the Original Aspiration and Keeping Mission Firmly in Mind'*.

June 20-25 — PhIRDA Delegation, led by Executive President Song Ruilin, visited the innovation industrial parks, medical research centers, research institutes, universities and innovative companies in the Netherlands and Germany, and signed a MOU with Sino German Hi-Tech Park.

June 24 Chengdu Easton Biopharmaceuticals Co., Ltd and Xtalpi Inc. officially joined PhIRDA.

June 27 The 2019 International Innovative Clinical Research Conference, co-hosted by PhIRDA, Chinese Cardiovascular Association (CCA) etc., was successfully held in Hangzhou.

June 27 PhIRDA signed a strategic cooperation agreement with the New England Journal of Medicine (NEJM) in Hangzhou.

July 3 The Review Meeting of 2019 'Dushu Lake Prize' Selection Activities of China Pharmaceutical Innovation Brand was held in Beijing and released the list of project nominees.

July 15 PhIRDA signed a cooperation agreement on pharmaceutical innovation and development with People's Government of Shandong Province.

July 18 The 2019 PhIRDA Contact Representative Meeting was held in Harbin.

July 19 The 10th China Hospital Pharmacy Policy Forum, co-hosted by PhIRDA, Chinese Pharmacists Association (CPA) and Chinese Hospital Association (CHA) was successfully held in Harbin.

July 25 PhIRDA signed cooperation agreement with People's Government of Pingshan District, Shenzhen Municipality to jointly promote China's pharmaceutical innovation and to co-build a highland for biological medicine in the Guangdong-Hong Kong-Macao Greater Bay Area.

September 20 The 11th General Assembly of PhIRDA was held in Suzhou.

September 20 Beijing Clinical Service Center and 3H Health Investment Management Ltd. officially joined PhIRDA.

September 20 The first meeting of the 11th Board of Directors was held in Suzhou. Song Ruilin was elected as 2019-2020 PhIRDA Annual Chairman.

September 21 The Final Meeting and Award Ceremony for '2019 Dushu Lake Prize' Selection Activities of China Pharmaceutical Innovation Brand were held at Broadcasting Hall of Suzhou Broadcasting System (SBS).

September21-23 The 2019 China BioMed Innovation and Investment Conference (CBIIC), hosted by PhIRDA, CAMDI, CHA, HKEX and RDI was held in Suzhou Industrial Park (SIP).

September 23 PhIRDA Chairman Song Ruilin met with Douglas Bingeman, Consul & Trade Commissioner of Consulate General of Canada in Shanghai.