

中国制药及 医疗器械领域 伦理合作共识框架



中国化学制药工业协会

(2017年7月6日)

中国制药及医疗器械领域伦理合作共识框架

一、背景

2013年10月29日，中国化学制药工业协会、中国医药保健品进出口商会、中国外商投资企业协会药品研制和开发行业委员会、中国医药工业科研开发促进会、中国中药协会、中国医药商业协会、中国非处方药物协会、中国医药企业发展促进会、中国医药企业文化建设协会共计9家医药协会商会共同主办了“中国医药企业伦理准则发布大会”，联合签署了实施《医药企业伦理准则》倡议书，倡议医药界同仁遵循各项条款。

2015年，中华全国工商业联合会医药业商会、中国医疗器械行业协会、中国医药包装协会、中国医药教育协会、中国医药企业管理协会、中国医药设备工程协会、中国医药生物技术协会和中国医药质量管理协会8家协会签署了实施《医药企业伦理准则》倡议书。至此，全国共有17家医药相关协会商会加入到了倡导《医药企业伦理准则》的行列中来。中华医学会、中国药学会、中国医师协会和中国医院协会也与上述17家协会商会达成共识，使各自的行为规范相互衔接。

2018年7月6日，在工业和信息化部、商务部、国家药品监督管理局、国家中医药管理局等行业指导及监管部门的支持下，中国化学制药工业协会、中国医药保健品进出口商会、中国外商投资企业协会药品研制和开发行业委员会、中国中药协会、中国医药创新促进会、中国医药商业协会、中国非处方药物协会、中国医院协会、中国医药企业发展促进会、中国医疗器械行业协会、中国医药生物技术协会、中国医药包装协会、中国医药设备工程协会、中国生化制药工业协会、中国非公立医疗机构协会、北京药盾公益基金会、北京医药行业协会、上海医药行业协会、河北省医药行业协会、山东省医药行业协会、江苏省医药行业协会、陕西省医药协会、辽宁省医药行业协会、福建省医药行业协会、浙江省医药

行业协会共同签署《中国制药及医疗器械领域伦理合作共识框架》（以下简称为《共识框架》）。

二、宗旨

根据适用于制药及医疗器械领域的亚太经合组织各项原则，联合中国医药卫生系统相关制药及医疗器械领域的协会和商会、医疗卫生领域的专业人士和相关协会等各方（以下简称为“各方”），承认《共识框架》，以指导并加强医药和医疗器械生产销售企业、相关行业协会、医疗卫生专业人士和政府机关之间的交流，增强相互之间的信任。

1. 设计相关机制，促进各方开诚布公地沟通、交流；
2. 根据现有《共识框架》且在现有法律体系范围内，吸收和采纳行业内已较成熟的行为准则和规范，促进各方共同制定或统一伦理准则，提升公信力；
3. 制定各方共享的能力建设与培训计划；
4. 打造一个有利环境，促进各方尽早发现共同面临的挑战，并开展相关合作，以便真正探讨如何改善医疗成效和患者疗效。

三、承诺

1. 以人为本

秉持“以人为本，以患者为中心”的理念，协力确保全民健康福祉在各项活动中始终处于核心地位。各方通过在《共识框架》下开展合作，共同落实高标准的道德实践，从而促进全民医疗事业的发展。

2. 加强合作

各方的交流应始终合乎道德、合法、适当且专业。各方承诺采用透明的方式，以促进信任、提高人民健康福利、改善服务为目标，协力落实适用于制药和医疗器械领域的亚太经合组织原则。各方的有效合作将推动医疗创新、提高医疗成效。

3. 尊重差异

各方的所有活动均应尊重文化、性别、背景差异，且没有歧视。

四、机制

1. 能力建设与培训

加强从业人员培训和能力建设。在现有行业专业培训先进经验的基础上，推广高水平的从业人员能力培训和测试项目，加强医药代表和其他从业人员的管理，让更多的从业人员可以通过培训学习理解伦理准则的精髓，提升道德意识，以便更好地在工作中践行伦理准则。

建立和优化线上培训系统，通过开展继续教育来进一步补充从业人员能力建设的持续性和进阶性。

2. 行为约束

制定明确规则，帮助建立信任并加强各方的合作。各方承诺不在供应链、处方、配方以及医药和医疗器械产品的使用中宣传不当诱因，遵守高标准的行业伦理准则和行为规范。

3. 动态汇报

暂定各方每两年举办一次高层代表会议，讨论《共识框架》的实施情况。会议期间，各方将制定联合工作计划，明确为加强道德实践将开展的所有活动。《共识框架》属于动态文件，欢迎相关领域的其他组织加入。

4. 实施问责

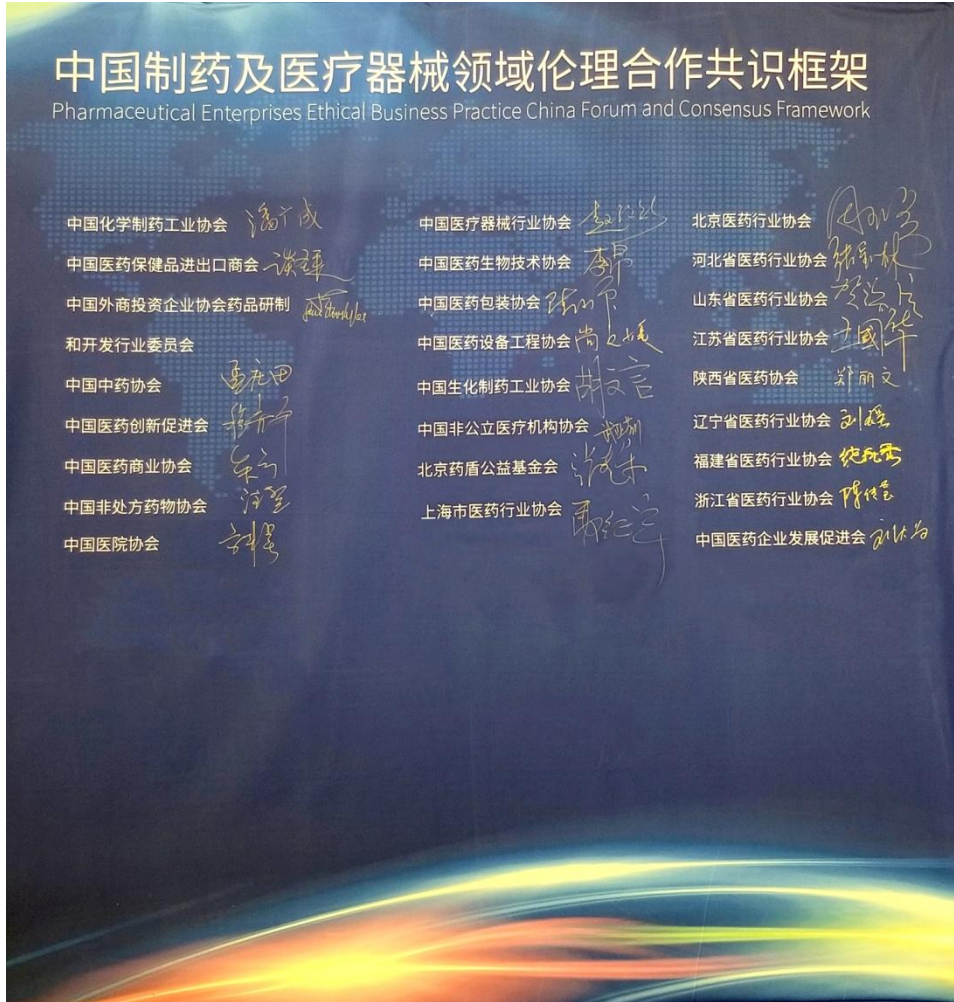
各方将不断完善《共识框架》，并确保其实施。尝试制定会员教育制度和违规汇报与处理制度，来支持道德准则的践行。

各方均应遵循伦理准则中的价值观和责任观，以专业的标准，维护其组织和职业的诚信，避免开展导致利益冲突和违法违规的任何活动。

五、签署

下列各方承认并签署《共识框架》，确保中国医药和医疗器械生产销售企业、相关行业协会、医疗卫生专业人士的合作，以有道德且负责任的决策为基础，符合各方利益。

中国化学制药工业协会	中国医药设备工程协会
中国医药保健品进出口商会	中国生化制药工业协会
中国外商投资企业协会药品研制和开发行业委员会	中国非公立医疗机构协会
中国中药协会	北京药盾公益基金会
中国医药创新促进会	北京医药行业协会
中国医药商业协会	上海医药行业协会
中国非处方药物协会	河北省医药行业协会
中国医院协会	山东省医药行业协会
中国医药企业发展促进会	江苏省医药行业协会
中国医疗器械行业协会	陕西省医药协会
中国医药生物技术协会	辽宁省医药行业协会
中国医药包装协会	福建省医药行业协会
	浙江省医药行业协会



CHINESE

CONSENSUS FRAMEWORK FOR THE ETHICAL COLLABORATION

IN THE PHARMACEUTICAL
AND MEDICAL DEVICE
SECTORS



China Pharmaceutical Industry Association

(July 6, 2018)

CONTEXT

On October 29th, 2013, nine local pharmaceutical organizations co-held the “Launch Meeting of the Code of Ethics for Pharmaceutical Enterprises in China”, and co-signed an initiative for implementing the Code of Ethics for Pharmaceutical Enterprises in China, requiring all stakeholders in Chinese pharmaceutical industry to abide by relevant provisions. The nine organizations are China Pharmaceutical Industry Association (CPIA), China Chamber of Commerce for Import & Export of Medicines & Health Products (CCCMHPIE), R&D-based Pharmaceutical Association Committee of China Association of Enterprises with Foreign Investment (RDPAC), China Pharmaceutical Innovation and Research Development Association (PhIRDA), China Association of Traditional Chinese Medicine (CATCM), China Association of Pharmaceutical Commerce (CAPC), China Nonprescription Medicines Association (CNMA), China Pharmaceutical Enterprises Development Promote Association (CPEP), and China Pharmaceutical Enterprises Culture Construction Association (CPECCA).

In 2015, eight more associations signed the above-mentioned initiative. The eight associations are All-China Chamber of Commerce for Medical and Pharmaceutical Industries (CMP), China Association for Medical Devices Industry (CAMDI), China National Pharmaceutical Packaging Association (CNPPA), China Medical Education Association (CMEA), Chinese Pharmaceutical Enterprises Association (CPEA), China Pharmaceutical Association of Plant Engineering (CPAPE), China Medicinal Biotech Association (CMBA), and China Quality Association for Pharmaceuticals (CQAP). So far, 17 pharmaceutical organizations have joined together in the movement of promoting the Code of Ethics for Pharmaceutical Enterprises in China. Chinese Medical Association (CMA), Chinese Pharmaceutical Association (CPA), Chinese Medical Doctor Association (CMDA) and Chinese Hospital Association (CHA) have also reached a consensus, trying to reach a convergence among their own codes of practices.

On July 6, 2018, with the support from government agencies that guide and monitor the development of the pharmaceutical industry in China, such as Ministry of Industry and Information Technology, Ministry of Commerce, China National Drug Administration, State Administration of Traditional Chinese Medicine, China Pharmaceutical Industry Association (CPIA), China Chamber of Commerce for Import & Export of Medicines & Health Products (CCCMHPIE), R&D-based Pharmaceutical Association Committee of China Association of Enterprises with Foreign Investment (RDPAC), China Association of Traditional Chinese Medicine (CATCM), China Pharmaceutical Innovation and Research Development Association (PhIRDA), China Association of Pharmaceutical Commerce (CAPC), China

Medicines Association(CNMA), Chinese Hospital Association(CHA), China Pharmaceutical Enterprises Development Promote Association (CPEP), China Association for Medical Devices Industry (CAMDI), China Medicinal Biotech Association (CMBA), China National Pharmaceutical Packaging Association (CNPPA), China Pharmaceutical Association of Plant Engineering (CPAPE), China Biochemical Pharmaceutical Industry Association (CBPIA), Chinese Non-government Medical Institutions Association (CNMIA), PSM Foundation, Beijing Pharmaceutical Profession Association (BPPA), Shanghai Pharmaceutical Profession Association (SPPA), Hebei Pharmaceutical Profession Association (HBPPA), Shandong Pharmaceutical Profession Association (SDPPA), Jiangsu Pharmaceutical Profession Association (JSPPA), Shaanxi Pharmaceutical Profession Association (SPPA), Liaoning Pharmaceutical Profession Association (LNPPA), Fujian Pharmaceutical Profession Association (FJPPA), and Zhejiang Pharmaceutical Industry Association (ZJPIA) co-signed *Chinese Consensus Framework for the Ethical Collaboration in the Pharmaceutical and Medical Device Sectors*” (hereinafter referred to as “the Framework”).

PURPOSE

Organizations in the pharmaceutical and medical device sectors, medical and health care professionals, related associations etc. (hereinafter referred to as “the Parties”) endorse the Framework to guide and strengthen interactions among pharmaceutical and medical device enterprises of production and sales and their industry associations, health care professionals, and government agencies, and to build trust among the Parties, based on the APEC Principles developed for the biopharmaceutical and medical device sectors.

1. Design mechanisms to facilitate open communication and interaction among the Parties;
2. Promote the mutual development and/or alignment of codes of ethics among the Parties based on the present Framework and the existing legal system, as well as the experience drawn from the mature codes of practice in pharmaceutical industry, and strengthen public confidence in them;
3. Develop the capacity-building and training programs among the Parties;
4. Create an environment to promote the early identification of and collaboration on shared challenges, to have authentic discussions about improving health care and patient outcomes.

COMMITMENT

1. People-Oriented

People and patients are our first priority, so we will work together to ensure that public health benefits are at the core of all activities. Through collaboration under the Framework, the Parties will embrace high standard ethical practices to advance health care.

2. Strengthened Collaboration

Interactions among the Parties are always ethical, legitimate, appropriate and professional. The Parties are committed to collaboration in implementing the APEC Principles developed for the pharmaceutical and medical device sectors in a manner that is transparent and that aims to inspire trust, deliver greater benefits and services to people's health. The collaboration among the Parties will drive health care innovation and generate improved health care outcomes.

3. Respecting Differences

All activities of the Parties should respect diversities in culture, gender and background without any discrimination.

MECHANISM

1. Capacity Building & Training

Strengthen capacity-building and professional trainings by learning the experience from the advanced training programs of pharmaceutical industry, promoting the capacity training and test schemes, strengthening the management of MRs and other practitioners, so that more related professionals will have access to the code of ethics by their learning to improve their ethic awareness, which will help them better implement the code of ethics in their daily work.

Establish and optimize virtual training systems, with the aim of enhancing and improving the capacity-building of related professionals continuously.

2. Conduct Restriction

Develop clear code of ethics to build trust and strengthen collaboration among the Parties. The Parties commit not to promote improper inducements within the supply chain, prescription, dispensation, or use of pharmaceutical and medical device products, and abide by the high standard code of conduct and ethical standards of pharmaceutical industry.

3. Timely Updates

The provisional plan is to hold an annual meeting of senior representatives from the Parties to discuss implementation of the Framework. During the meeting, the Parties will develop a joint work plan that details all activities to strengthen ethical practices. The Framework is a living document, and other organizations in relevant sectors are welcome to endorse it.

4. Accountability

The Parties will continue to develop the Framework and ensure its implementation. Systems to educate our members and to report and act on breaches may be established to support the implementation of the code of ethics.

The Parties should abide by the values of the code of ethics and take necessary responsibilities to protect the integrity of our organizations and professions in a professional manner. Any activity that may lead to benefit conflict or breaches should be avoided.

ENDORSEMENT

The Framework is endorsed and signed by the Parties indicated. The Parties have a mutual interest to ensure that the collaboration among pharmaceutical and medical device enterprises of production and sales and their industry associations, and health care professionals are based on ethical and responsible decisions.

China Pharmaceutical Industry Association (CPIA)

China Chamber of Commerce for Import & Export of Medicines & Health Products (CCCMHPIE)

R&D-based Pharmaceutical Association Committee of China Association of Enterprises with Foreign Investment (RDPAC)

China Association of Traditional Chinese Medicine (CATCM)

China Pharmaceutical Innovation and Research Development Association (PhIRDA)

China Association of Pharmaceutical Commerce (CAPC)

China Nonprescription Medicines Association (CNMA)

Chinese Hospital Association (CHA)

China Pharmaceutical Enterprises Development Promote Association (CPEP)

China Association for Medical Devices Industry (CAMDI)

China Medicinal Biotech Association (CMBA)

China National Pharmaceutical Packaging Association (CNPPA)

China Pharmaceutical Association of Plant Engineering (CPAPE)

China Biochemical Pharmaceutical Industry Association (CBPIA)

Chinese Non-government Medical Institutions Association (CNMIA)

PSM Foundation

Beijing Pharmaceutical Profession Association (BPPA)

Shanghai Pharmaceutical Profession Association (SPPA)

Hebei Pharmaceutical Profession Association (HBPPA)

Shandong Pharmaceutical Profession Association (SDPPA)

Jiangsu Pharmaceutical Profession Association (JSPPA)

Shaanxi Pharmaceutical Profession Association (SPPA)

Liaoning Pharmaceutical Profession Association (LNPPA)

Fujian Pharmaceutical Profession Association (FJPPA)

Zhejiang Pharmaceutical Industry Association (ZJPIA)

