

2019 SUMMARY REPORT ON CODE OF ETHICS IMPLEMENTATION BY CHINA BIOPHARMACEUTICAL INDUSTRY ASSOCIATIONS

This report summarizes the results of the first survey on code of ethics implementation by China's biopharmaceutical industry associations that signed the *Consensus Framework for the Ethical Collaboration in the Pharmaceutical and Medical Device Sectors* ("the Framework").¹ The data represent responses from 13 of the 25 Framework signatories. The survey aims to provide baseline information that may be used to gauge the biopharmaceutical industry associations' capacity to implement the Framework. The data highlighted in this report measures the progress of the industry associations' capacity-building efforts across **three key areas** of effective code implementation: **(1) code governance**, **(2) alignment with the APEC Mexico City Principles**, and **(3) stakeholder engagement**.

SUMMARY OF KEY FINDINGS

- 85% of respondents recognize the importance of business ethics for the industry's future, stating that high ethical standards will benefit their membership.
- While nearly all respondents understand the concept of business ethics guidelines related to the biopharmaceutical industry, 46% understand the concept "very well."
- Respondents are keen to build capacity, with nearly all expressing interest in training activities to develop business ethics guidelines and 83% already providing training.
- 55% of respondents have officially adopted ethical guidelines.
- 45% of respondents have not adopted ethical guidelines. Of those, 71% are actively considering adopting ethical guidelines.
- A majority of respondents require more resources to cope with changes brought about by the implementation of ethical guidelines.
- Nearly all respondents are aware of the APEC Mexico City Principles.
- A large majority of respondents prefer promoting common principles (47%) or government partnership (40%) to achieve alignment in ethical guidelines between associations, rather than forming an ethics committee between associations (17%).

DETAILED FINDINGS

CODE GOVERNANCE

Codes of ethics are an effective means of informing biopharmaceutical enterprises about ethical business practices. However, codes of ethics are only as effective as the code governance that is put in place. This assessment aims to identify where code governance exists by biopharmaceutical industry associations in China, as well as potential areas for future growth. The below chart highlights the results:

¹ http://mcprinciples.org/CMFiles/Chinese_Consensus_Framework.pdf

Question	% "Yes" Response / Total
Do you understand the concept of business ethics guidelines related to the biopharmaceutical industry?	92%
Do you very well understand the concept of business ethics guidelines related to the biopharmaceutical industry?	46%
Is your association interested in training activities to develop business ethics guidelines?	92%
If your association is interested in training activities, has your association provided training for business ethics guidelines for member units?	83%
Has your association officially adopted the ethical guidelines?	55%
If your association has not officially adopted the ethical guidelines, does your association actively consider implementing ethical guidelines?	71%
Does your association have a designated employee (including part-time) responsible for supervising implementation of the ethics guidelines?	62%
Is your association interested in the implementation of business ethics?	92%
If your association is interested in implementation of business ethics, would your associations need substantially more resources to cope with changes brought about by the implementation of the ethics guidelines?	62%

ALIGNMENT WITH APEC MEXICO CITY PRINCIPLES

The Framework's guidance is largely based on the APEC Mexico City Principles and APEC Kuala Lumpur Principles. The APEC Mexico City Principles promote the adoption and implementation of voluntary codes of business ethics for the biopharmaceutical sector. Of the associations surveyed, **92%** confirmed that they are aware of the APEC Mexico City Principles. **100%** of the respondents said they are aware of the Framework and that the association signed it in 2018. When asked whether their association promotes the APEC Mexico City Principles as a guide to ethical interactions between healthcare professionals and the biopharmaceutical industry over the past two years, **67%** said that promoted the Principles within the last one or two years.

STAKEHOLDER ENGAGEMENT

Stakeholder engagement is necessary for effective promotion of ethical business practices across the biopharmaceutical industry. Engagement can occur both internally (between enterprises and associations) and externally (between the industry and governments, healthcare professional groups, health providers). Both forms of stakeholder engagement help to promote sector development vis-à-vis ethical business practices and patient-centered care. When asked to select an approach that their association would be willing to support in order to ensure consistent ethical guidelines between different industry groups, **47%** chose "Promote trust as the most important goal by following the 'moral idea' approach of common principles among associations." Another **40%** chose "Establish partnerships with the government to implement consistent ethical guidelines." And only **17%** expressed interest in establishing a recognized ethics committee between associations.

When asked to rank four different action items for future cooperation between associations there was not a majority consensus on which action should be prioritized first. **40%** ranked first “Promote the common development and/or coordination of the ethical guidelines of the signatories on the basis of the existing framework and the existing legal system, draw on the experience of the pharmaceutical industry in the practice of mature ethical standards, and enhance public confidence in business ethics.” The rest of the respondents were evenly split between the other actions items; **20%** ranked each first. These other items included:

- “Design a mechanism to promote open communication and interaction between signatories;”
- “Develop capacity building and training programmes for each signatory;” and
- “Create an environment for early identification and common difficulties, and discuss issues such as improving medical health and patient status.”

FRAMEWORK CO-SIGNEES

Association	Total Membership	SME Membership	Survey Respondent?
China Pharmaceutical Industry Association (CPIA)	460	150	Yes
China Chamber of Commerce for Import and Export of Medicines & Health Products (CCCMPHIE)	1650	1485	Yes
R&D-based Pharmaceutical Association Committee of China Association of Enterprises with Foreign Investment (RDPAC)	43	0	Yes
China Pharmaceutical Innovation and Research Development Association (PhIRDA)	87	19	Yes
China Pharmaceutical Enterprises Development Promote Association (CPEP)	150	-	Yes
China Association for Medical Devices Industry (CAMDI)	-	-	Yes
China Medicinal Biotech Association (CMBA)	300	250	Yes
China National Pharmaceutical Packaging Association (CNPPA)	37	-	Yes
PSM Foundation	-	-	Yes
Shanghai Pharmaceutical Profession Association (SPPA)	-	-	Yes
Hebei Pharmaceutical Profession Association (HBPPA)	-	-	Yes
Jiangsu Pharmaceutical Profession Association (JSPPA)	20	-	Yes
Liaoning Pharmaceutical Profession Association (LNPPA)	9	6	Yes
China Association of Traditional Chinese Medicine (CATCM)	700	500	No
China Association of Pharmaceutical Commerce (CAPC)	384	249	No
China Nonprescription Medicines Association	350	-	No

(CNMA)			
Chinese Hospital Association (CHA)	-	-	No
China Pharmaceutical Association of Plant Engineering (CPAPE)	350	-	No
China Biochemical Pharmaceutical Industry Association (CBPIA)	-	-	No
Chinese Non-government Medical Institutions Association (CNMIA)	-	-	No
Beijing Pharmaceutical Profession Association (BPPA)	-	-	No
Shandong Pharmaceutical Profession Association (SDPPA)	-	-	No
Shaanxi Pharmaceutical Profession Association (SPPA)	-	-	No
Fujian Pharmaceutical Profession Association (FJPPA)	-	-	No
Zhejiang Pharmaceutical Industry Association (ZJPIA)	-	-	No

2019中国制药行业协会伦理准则实施总结报告

日前中国签署《中国制药及医疗器械领域伦理合作共识框架》（以下简称《共识框架》）²的制药行业协会针对伦理准则的实施情况进行了首次问卷调查，本报告汇总了此次调查问卷的结果。《共识框架》25家签署方中，有13家填写了问卷，以下数据均以此为基础。此次问卷调查旨在提供基准信息，可用其衡量中国制药行业协会实施伦理准则的能力。本报告中重点提及的数据展示了行业协会在有效实施伦理准则的**三个关键领域**中能力建设工作的进展情况，这三个领域包括：**（1）准则的管理；（2）与 APEC《墨西哥城原则》的一致性；以及（3）利益相关方的参与。**

² http://mcprinciples.org/CMFiles/Chinese_Consensus_Framework.pdf

主要调查结果摘要

- 85%的受访者认识到商业伦理对于行业未来的重要性，认为高标准商业伦理准则会令其会员单位受益。
- 几乎所有受访者都了解与生物制药行业相关的商业伦理准则概念，其中46% “很了解” 这一概念。
- 受访者热衷于能力建设，几乎所有受访者都表示对开展培训活动来推动商业伦理准则的实施感兴趣，有83%已提供了相关培训。
- 55%的受访者已经正式推行了伦理准则，尚未推行伦理准则的受访者中，有71%积极考虑推行伦理准则。
- 大部分受访者需要更多资源来应对商业伦理准则实施所带来的变革。
- 几乎所有的受访者都了解APEC《墨西哥城原则》。
- 绝大多数受访者倾向于通过推行共同的原则（47%）或与政府建立合作伙伴关系（40%），来实现不同的制药行业协会之间推行一致的伦理准则这一目标，而非通过在协会间建立伦理准则委员会（17%）。

详细调查结果

准则的管理

伦理准则是向生物制药企业宣贯商业伦理实践的有效手段。然而，伦理准则只有在实行准则管理时才是有效的。本项评估旨在让中国的生物制药行业协会指出，准则的管理存在于何处，以及未来发展的潜在领域。重点结果见下表：

问题	给出肯定回答的百分比
您是否了解与生物制药行业相关的商业伦理准则概念？	92%
您是否很了解与生物制药行业相关的商业伦理准则概念？	46%
贵协会是否对开展商业伦理准则的培训活动感兴趣？	92%
贵协会若对开展商业伦理准则的培训活动感兴趣，是否已为会员单位提供了商业伦理准则培训？	83%
贵协会是否正式推行了伦理准则？	55%
贵协会若尚未正式推行伦理准则，是否积极考虑推行伦理准则？	71%
贵协会是否有指定的员工（包括兼职）负责监督伦理准则的实施情况？	62%
贵协会是否对商业伦理准则的实施感兴趣？	92%
贵协会若对商业伦理准则的实施感兴趣，是否需要更多资源来应对商业伦理准则实施所带来的变革？	62%

与 APEC 《墨西哥城原则》的一致性

《共识框架》的指导原则主要基于APEC《墨西哥城原则》和APEC《吉隆坡原则》。APEC《墨西哥城原则》推动生物制药领域采纳和实施带有自愿性质的商业伦理准则。受访协会中，92%确认他们了解APEC《墨西哥城原则》。100%的受访者表示他们了解《共识框架》，其所在协会于2018年签署了《共识框架》。在被问及其所在协会是否在过去两年间推广过APEC《墨西哥城原则》这一医疗卫生领域和生物制药行业间合乎道德操守的互动的指南时，67%的受访者表示，他们在过去一两年间推广过《墨西哥城原则》。

利益相关方的参与

利益相关方的参与对于在生物制药行业有效推广商业伦理实践而言十分必要。参与可以是内部的（企业和协会之间），也可以是外部的（行业和政府、医疗卫生专业人士团体、医疗服务提供者之间）。这两种形式的利益相关方的参与都有助于在商业伦理实践和以患者为中心的医疗服务的基础上，促进行业发展。在被问及为确保中国不同的行业组织之间推行一致的伦理准则，协会愿意支持哪种方法时，47%选择“遵

循协会之间具有共同原则的‘道德理念’方法，将促进信任作为最重要的目标”；另有40%选择“与政府建立合作伙伴关系，以实施一致的伦理准则”；只有17%表示对“建立协会之间公认的伦理准则委员会”感兴趣。

在被要求给未来协会间合作的四个行动项目进行排序时，未能就优先开展哪项行动达成多数人的共识。40%将“在现有框架和现有法律体系的基础上，促进各签署方伦理准则的共同发展和/或协调，汲取制药行业在成熟伦理标准实践方面的经验，增强公众对商业伦理准则的信心”排在首位。剩余几项行动项目平分秋色，各有20%的受访者将其排在首位。这几个行动项目分别是：

- “设计促进各签署方之间开放式沟通与互动交流的机制；”
- “为各签署方制定能力建设和培训方案；” 以及
- “创建早期识别、共同克服困难的环境，就改善医疗健康和患者状况等问题进行协商讨论。”

《共识框架》签署方（排名不分先后）

单位名称	会员单位数量	中小企业会员单位数量	是否填写调查问卷
中国化学制药工业协会	460	150	是
中国医药保健品进出口商会	1650	1485	是
中国外商投资企业协会药品研制和开发行业委员会	43	0	是
中国医药创新促进会	87	19	是
中国医药企业发展促进会	150	-	是
中国医疗器械行业协会	-	-	是
中国医药生物技术协会	300	250	是
中国医药包装协会	37	-	是
北京药盾公益基金会	-	-	是
上海医药行业协会	-	-	是
河北省医药行业协会	-	-	是
江苏省医药行业协会	20	-	是
辽宁省医药行业协会	9	6	是
中国中药协会	700	500	否
中国医药商业协会	384	249	否
中国非处方药物协会	350	-	否
中国医院协会	-	-	否
中国医药设备工程协会	350	-	否
中国生化制药工业协会	-	-	否
中国非公立医疗机构协会	-	-	否
北京医药行业协会	-	-	否
山东省医药行业协会	-	-	否
陕西省医药协会	-	-	否
福建省医药行业协会	-	-	否
浙江省医药行业协会	-	-	否