

Korea Pharmaceutical Manufacturers Association

Code of Practices

Established on July 23, 2014

Article 1. (Purpose)

① The purpose of this Korea Pharmaceutical Manufacturers Association (the “**KPMA**”) Code of Practices (this “**Code of Practices**”) is to establish compliant management, ethical management and transparent management within member pharmaceutical companies (the “**Members**”) and ultimately contribute to social development and improvement of patient welfare by specifying in detail the principles set forth in the KPMA Principles on Business Ethics (the “**Ethics Principles**”).

② The Members of the KPMA shall conduct business activities in compliance with the relevant laws and regulations including the Pharmaceutical Affairs Act (the “**PAA**”), the Ethics Principles and the Fair Competition Code on Transaction of Pharmaceuticals and its Working Guidelines.

Article 2. (Definition)

Article 3 of the Fair Competition Code on Transaction of Pharmaceuticals shall apply mutatis mutandis to the terms used under this Code of Practices unless otherwise defined.

Article 3. (General Obligations of the Members)

① The Members shall acknowledge the responsibilities of pharmaceutical companies set forth under the Ethics Principles as obligations they should voluntarily comply with, take initiative in the performance of such obligations, and exert efforts to ensure the acts of their officers and employees are conducted pursuant to responsible management and supervision. In particular, the Members shall ensure that all of its officers and employees are sufficiently aware of, and thereby comply with, the terms of the relevant laws and regulations including the Fair Competition Code on Transaction of Pharmaceuticals.

② The Members shall seek to prevent and treat the variety of diseases existing in modern society, and fully commit to research and development of new drugs to treat diseases for which treatment has yet to be developed. Further, the Members shall select research and development strategies suitable to their respective development stages such as pursuing incrementally modified drugs, new drugs, innovative drugs, etc., to seek independent ways to make a contribution.

③ The Members shall exert efforts to ensure medical expenditures are made in a cost-

efficient manner through efficient production of pharmaceuticals. In order to achieve the foregoing, the Members are imposed with the responsibility to supply economical and high-quality pharmaceuticals by conducting reliable clinical trials and exerting best efforts towards quality management. The Members shall clearly recognize that they are able to contribute to the soundness of public finance by improving cost-efficiency, and that they are able to contribute to the overall enhancement of national wealth by improving the public's quality of life.

④ The Members shall deeply reflect on the importance of pharmaceuticals in terms of people's health and shall be obligated to conduct business activities which prioritize pharmaceutical safety and prevention of harm from adverse reactions throughout the entire process, from research and development to manufacturing and sales. In particular, the Members shall ensure consumer's judgment can be based on sufficient information through the establishment of pharmacovigilance systems and proper labeling.

⑤ The Members have the duty to provide a stable supply of pharmaceuticals which is directly related to the people's health, and shall not deem pharmaceuticals solely as profit-making tools. The Members shall always bear in mind that ensuring consumer's accessibility to pharmaceuticals is the mission of pharmaceutical companies and the reason for their existence.

⑥ The Members shall conduct business activities by not only complying with domestic laws and regulations but also respecting various international standards regarding anti-corruption, human rights, the environment, etc. In particular, the Members shall be opposed to unreasonable discrimination based on race, gender, religion, values, beliefs, etc., respect motherhood and repudiate exploitation of child labor.

⑦ The Members shall properly manage and preserve personal information acquired in the course of their business activities, and shall disclose internal information to stakeholders, etc., by means consistent with the relevant laws and regulations. In particular, in light of the importance of medical relationships, the Members shall bear in mind that the information acquired regarding consumers or clinical trial participants may be classified as sensitive information and exert best efforts to protect such information.

⑧ The Members shall recognize that the establishment of integrity through anti-corruption efforts is an indispensable condition to the development of business ethics. The Members shall exert best efforts to prevent relationships based on exchange of economic benefits in connection to job positions or requests in their relationships with the government or public institutions.

⑨ The Members shall exert efforts to identify the cause and prevent reoccurrence of any incident that occurs which is contrary to the spirit of this Code of Practices. Such identification and prevention efforts shall include internal investigations, sanctions such as disciplinary measures against the violator, adequate education and training, establishment of prevention systems, etc.

⑩ The Members shall conduct continuous education and training sessions for their officers and employees with regard to relevant laws and regulations, the Ethics Principles, the Fair Competition Code on Transaction of Pharmaceuticals and this Code of Practices.

⑪ The Members shall ensure that all of their officers and employees conduct their work based on the spirit of this Code of Practices.

⑫ In case the Members have affiliated companies such as subsidiaries which are related to pharmaceutical transactions, the Members shall also ensure such companies' compliance to this Code of Practices.

⑬ The Members shall also ensure third parties or institutions which conduct work entrusted by the Members will comply with this Code of Practices.

Article 4. (Establishment of Internal Regulations and Appointment of Voluntary Compliance Officer)

① In order to comply with the relevant laws and regulations, the Ethics Principles, the Fair Competition Code on Transaction of Pharmaceuticals and this Code of Practices, the Members shall set forth proper standards and procedures (the “**Internal Regulations**”) that officers and employees need to comply with in the course of performing their work.

② The Members shall appoint a person or establish a department responsible for the investigation and reporting of the status of compliance and violation of relevant laws and regulations, the Fair Competition Code on the Transaction of Pharmaceuticals and the Internal Regulations (the “**Voluntary Compliance Officer**”) by officers and employees.

③ The Members shall appoint a person with appropriate knowledge and qualifications for performing the relevant scope of work as Voluntary Compliance Officer.

④ The Voluntary Compliance Officer shall perform his/her duties with due care as a prudent manager.

⑤ The Members shall recognize the independence of the Voluntary Compliance Officer in terms of organization, personnel and budget, to ensure the Voluntary Compliance Officer can perform his/her duties independently.

⑥ The officers and employees of the Members shall comply in good faith with requests for submission of materials and information by the Voluntary Compliance Officer in the course of performing his/her work.

⑦ In case the Voluntary Compliance Officer intends to conduct education and training sessions on the relevant laws and regulations, the Ethics Principles, the Fair Competition Code on Transaction of Pharmaceuticals and this Code of Practices, the Members shall provide sufficient support to ensure that appropriate education and training sessions are held.

⑧ In case of an occurrence of an incident that is contrary to the spirit of this Code of Practices, the Members shall accord due attention to the opinion of the Voluntary Compliance Officer and respect such opinion to the maximum extent possible in order to identify the cause and prevent reoccurrence of such incident.

⑨ The Members shall guarantee independence to ensure the Voluntary Compliance Officer can perform his/her work duties in a fair manner, and shall not impose any personnel-related or budgetary disadvantages in relation to his/her performance. In particular, the Members shall establish conditions such as establishing institutional systems to prevent the sales or marketing department from imposing improper influence on to the Voluntary Compliance Officer.

Article 5. (Standards for Provision of Pharmaceutical Information)

① The information distributed by the Members to promote pharmaceuticals (“**Pharmaceutical Information**”) shall be clear and accurate. Also, Pharmaceutical Information shall be the latest information available on the efficacy and risks of pharmaceuticals and be provided in the form of objective data to prevent information bias.

② Pharmaceutical Information shall not give rise to misunderstandings due to distortion, exaggeration, inappropriate emphasis or omission of information and the Members shall exert active efforts to prevent ambiguity.

③ Pharmaceutical Information shall be provable based on scientific evidence and such evidence shall be immediately provided to healthcare professionals, if requested.

④ In case of making references to Pharmaceutical Information included in academic materials, the source and meaning shall be clearly mentioned.

Article 6. (Preparation and Use of Promotional Materials)

① Printed advertisement, promotional brochures, leaflets and other printed materials prepared by the Members for the promotion of pharmaceuticals (“**Promotional Materials**”) shall include accurate information based on scientific evidence and prepared in a fair manner, as they are important tools for the provision of Pharmaceutical Information.

② The Members shall not describe any efficacy, effects, method of use or dosage which exceeds the scope approved by the Minister of Food & Drug Safety on the Promotional Materials.

③ The Members shall not include labels or expressions in the Promotional Materials that are false, exaggerated or can cause misunderstandings regarding the efficacy and safety of pharmaceuticals.

④ The Members shall not produce or distribute Promotional Materials which disparage other companies or the products of other companies.

⑤ The Members shall not use misleading expressions in the Promotional Materials that can be misread to mean that exceptional data and information mentioned in the Promotional Materials constitute generally accepted facts.

⑥ The Members shall not use photographs or designs which undermine the dignity of pharmaceuticals and shall be cautious in order to prevent healthcare professionals from misunderstanding the objective data due to distortion caused by such photographs or designs.

⑦ The Members shall establish an internal system for the management of Promotional Materials to provide accurate Pharmaceutical Information.

Article 7. (Preparation and Use of Electronic Promotional Materials)

① In case the Members conduct promotional activities on Internet websites, they shall comply with the following items

1. The promoter and the target audience of the promotional activity shall be clearly recognizable through the relevant website.
2. The content of the website shall be appropriate for the target audience.
3. The Members shall comply with laws and regulations related to advertisement through the website.

② In case promotional activities are conducted through websites with social media characteristics, the Members shall confirm the appropriateness of all postings including those contributed by third parties. Social media shall refer to media through which the exchange of opinions is made in the form of replies or other forms equivalent thereto on a real time basis.

③ Article 5 (Standards for Provision of Pharmaceutical Information) of this Code of Practices shall apply mutatis mutandis to standards applied in providing internet websites promotional materials, audio and video materials and other electronic promotional materials.

Article 8. (Work Attitude of Medical Representatives)

① “Medical Representatives” shall refer to officers and employees mainly responsible for the delivery of Pharmaceutical Information to healthcare professionals. Medical Representatives shall have sufficient medical and technical knowledge of pharmaceuticals and perform sales activities in a responsible manner.

② Medical Representatives shall assist healthcare professionals to ensure they are able to select and prescribe pharmaceuticals based on accurate and balanced information.

③ Medical Representatives shall not disparage other companies or the products of other companies in the course of his/her sales activities.

④ When visiting medical institutions, etc., Medical Representatives shall act in accordance with the rules of the relevant institutions.

⑤ The Members shall hold continuous education and training sessions to ensure that Medical Representatives can contribute to the proper use and supply of pharmaceuticals.

⑥ The Members shall not operate performance evaluation or compensation systems which may trigger the unethical behavior of Medical Representatives, and shall exert efforts to appropriately reflect Medical Representatives' sense of ethics and level of compliance to his/her performance-related evaluations and other treatment.

Article 9. (Provision of Money and Valuables)

The Members shall not provide nor promise to provide medical institutions or healthcare professionals with any money or valuables which may directly or indirectly influence the proper use of pharmaceuticals.

Article 10. (Donations)

Donations to medical institutions or healthcare professionals by the Members shall be made based on the following items and be approved within social norms, and shall be legitimately processed pursuant to Article 7 of the Fair Competition Code on Transaction of Pharmaceuticals.

1. Donations shall be made for medical · pharmaceutical, educational and charitable purposes.
2. Donations shall not be made for the purpose of inducing the selection, prescription or transaction of pharmaceuticals.
3. The donor shall record the details of donations and retain such information.

Article 11. (Support for Hosting Academic Conferences)

① The Members may provide support for the hosting of academic conferences which are held for the purpose of providing scientific · educational information related to medical science and pharmacology to healthcare professionals (“**Academic Conferences**”) and such support shall be provided for the purpose of supporting research, education, etc. through Academic Conferences.

② Academic Conferences supported by the Members shall have signs, etc. which clearly indicate that they were hosted with the support of the relevant Members.

③ The Members shall record the details of support provided to Academic Conferences and retain such information.

Article 12. (Product Presentations)

① The main purpose behind presentations on pharmaceuticals hosted by Members targeting healthcare professionals (“**Product Presentations**”) shall be the delivery of professional information on pharmaceuticals to the participants.

- ② Product Presentations held by the Members shall be hosted at venues suitable for the relevant purpose to ensure they are not misunderstood as unfair transactions, and the Members may provide participants with travel expenses, including transportation and lodging expenses, as well as meals and snacks within social norms pursuant to the Fair Competition Code on Transaction of Pharmaceuticals.
- ③ The Members are not permitted to provide travel expenses, etc. for those who accompany healthcare professionals to Academic Conferences.
- ④ The Members shall not provide healthcare professionals with money or valuables as compensation for possible business loss incurred from their participation at Product Presentations.
- ⑤ The Members shall record the details of support provided for Product Presentations and retain such information.

Article 13. (Support for Participation in Academic Conferences)

- ① The Members may provide travel expenses including transportation expenses, lodging expenses, etc. to healthcare professionals in case they participate in Academic Conferences for scientific · educational purposes.
- ② The Members are not permitted to support those who accompany healthcare professionals to Academic Conferences with travel expenses, etc.
- ③ Support for participation in Academic Conferences shall not be provided for the purpose of inducing the selection, prescription or transaction of pharmaceuticals.
- ④ The Members shall record the details of support provided for participation in Academic Conferences and retain such information.

Article 14. (Consultation and Lectures)

- ① The Members may request healthcare professionals with professional knowledge and experience in medical science and pharmacology to provide lectures or consultations.
- ② The Members may provide healthcare professionals with lecture fees or consultation fees within social norms based on the level of knowledge and experience as well as the content of lectures or consultations provided by the healthcare professionals.
- ③ In selecting healthcare professionals that the Members will make requests for lectures and consultations to, the Members shall rely on a reasonable standard which is established based on the level of expertise, knowledge, experience, etc. of such healthcare professionals.
- ④ The Members' requests for consultation or lectures shall not be for the purpose of inducing

the selection, prescription or transaction of pharmaceuticals.

Article 15. (Market Research)

- ① The Members may conduct market research for the purpose of collecting market-related materials.
- ② The Members may provide money or valuables as compensation for market research within social norms, but such provision shall not be for the purpose of inducing the selection, prescription or transaction of pharmaceuticals.

Article 16. (Post-Market Surveillance Study)

- ① Post-market surveillance studies (“PMS”) shall be conducted in accordance with the study purpose and content within the scope recognized as medically and pharmaceutically necessary.
- ② The number of case studies allotted to healthcare professionals participating in PMS shall be determined within a reasonable scope by taking into account whether the number of case studies is necessary to comply with reporting obligations prescribed under the PAA, number of patients treated by the healthcare professionals, etc.
- ③ The Members may provide study fees to healthcare professionals participating in PMS. However, the provision of such study fees shall not be for the purpose of inducing the selection, treatment or transaction of pharmaceuticals, or be excessive.

Article 17. (Provision of Samples)

The Members may provide samples to the minimum extent necessary for the confirmation and evaluation of the external characteristics, quality, efficacy and safety of the relevant product as a means to provide information on pharmaceuticals.

Article 18. (Clinical Trials)

- ① The clinical trials supported by the Members shall comply with the international standards for clinical trials at each stage as well as the relevant laws and regulations on clinical trials.
- ② The Members may conduct clinical trials for the purpose of acquiring valuable information in terms of medical science and pharmacology, provide pharmaceuticals for research purposes, and provide appropriate levels of research fees. Clinical trials must be performed for the purpose of improving patient welfare and based on a high level of ethics and legitimate scientific purpose.
- ③ The Members shall exert best efforts not to harm the health or infringe the rights of patients in the course of clinical trials, and always exert due care in order to respect patients’

human rights and secure their safety.

④ Clinical trials prescribed under this Article refer broadly to research conducted for the purpose of securing medically valuable information relating to pharmaceuticals, diseases or other healthcare fields which have structured data collection systems in place. Clinical trials prescribed under this Article shall not be limited to studies or research on pharmacokinetics, pharmacodynamics and clinical effects of the relevant pharmaceuticals or research of adverse reactions conducted for the purpose of proving the safety and efficacy of pharmaceuticals. The Members shall review the appropriateness and necessity of the research, the appropriateness of the method used to select the research institution, the method of securing reliability of the research results, appropriateness of the research method, etc., to ensure that the support for clinical trials is not used as a tool to make improper requests for the selection, transaction or prescription of pharmaceuticals.

Article 19. (Patient Support)

① The Members may provide medical and pharmaceutical information on diseases to patients or provide economic support to improve patient welfare.

② The Members shall take caution so that patient support is not used for the purpose of providing improper economic benefits to healthcare professionals, carrying out direct-to-consumer advertising of prescription drugs, soliciting or inducing medical institutions, preventing competitors' market entrance, etc. Patient support shall be in compliance with the Medical Services Act, the Monopoly Regulation and Fair Trade Act, the Personal Information Protection Act and other relevant laws and regulations.

Article 20. (Relationship with Patient Groups)

① The Members shall cooperate with patient groups based on a high standard of ethics and guarantee the independence of patient groups in the course of such cooperation.

② The Members shall exert efforts for sufficient and mutual understanding by the Members and patient groups regarding the purpose behind the cooperation and content of the cooperation.

③ The Members shall disclose the purpose and content of its economic support provided to patient groups and record the details of such support and retain such information.

④ The Members shall not use their relationship with patient groups for the purpose of inducing the selection, prescription or transaction of pharmaceuticals.

Article 21. (Personal Information Protection)

The Members shall collect, manage and protect personal information necessary in the course of their business activities in accordance with the Personal Information Protection Act and other relevant laws and regulations.

Article 22. (Overseas Business Activities)

The Members shall conduct business activities in accordance with the rules of the relevant country's pharmaceutical organization, if any, and if not, in accordance with the IFPMA Code of Practice.

Article 23. (Duties of the KPMA)

- ① The KPMA may actively recommend that the Members institute their own internal regulations based on the "Standard Internal Regulations" to establish a compliant and ethical management system, and may verify the Members' overall operational status.
- ② The KPMA shall operate a committee consisting of the Voluntary Compliance Officers of the Members in order to expand and establish compliant and ethical management.
- ③ The KPMA may impose sanctions on the Members in accordance with the procedures set forth in the Articles of Incorporation of the KPMA in case the Members violate relevant laws and regulations such as the Pharmaceutical Affairs Act, the KPMA Ethics Principles and this Code of Practices.
- ④ The KPMA shall adopt and implement a certification system for ethical companies by developing an evaluation index which reflects the characteristics and expertise of pharmaceutical industry.