



Shionogi Inc.

Comprehensive Compliance Program

Shionogi Inc. (“Shionogi”), a Delaware corporation, is committed to conducting its business in an ethical, compliant and responsible manner. This commitment is evident in the culture of the Company, which is established by Shionogi’s Board of Directors, Executive team, the Compliance Office and manifest itself in how each employee works and in our interaction with our customers, healthcare providers, patients and the public.

As part of its commitment to ethics and compliance, Shionogi has developed and maintains a Comprehensive Compliance Program (“CCP”) designed to promote compliance with federal and state statutes, regulations, codes and industry guidelines. The CCP is dynamic and specifically tailored to meet the unique structure and requirements of Shionogi.

Compliance with Applicable Laws and Standards

As set forth in Shionogi’s *Code of Conduct*, all Shionogi employees must comply with all Company policies, procedures, applicable laws, codes and regulations, including those related to the development, marketing, sale, and distribution of drug products. Shionogi employees must strictly adhere to federal and state fraud and abuse laws, including the Anti-Kickback statutes and False Claims Acts.

Additionally, Shionogi’s CCP incorporates and adheres to industry standards, codes, guidance and best practices in the area of compliance, including the *Compliance Program Guidance for Pharmaceutical Manufacturers*, developed by the United States Department of Health and Human Services’ Office of Inspector General (“OIG Guidance”), and the Pharmaceutical Research and Manufacturers of America (“PhRMA”) Revised *Code on Interactions with Health Care Professionals* (the “PhRMA Code”).

Written Policies and Procedures

Shionogi has established written policies and procedures, including but not limited to its *Code of Conduct*, *Compliance Field Manual*, and a comprehensive set of other compliance related policies and procedures. The Company’s written policies and procedures are designed to instruct and guide our employees, agents and consultants to comply with the laws and regulations, as well as to set forth the Company’s ethical standards. For example, the *Compliance Field Manual* is particularly designed to guide our field sales force on how to ethically, legally and responsibly interact with our customers on a variety of sale and marketing activities.

Compliance Officer and Compliance Committee

Shionogi has appointed a Compliance Officer who is charged with the oversight, monitoring, and the implementation of its CCP. The Compliance Officer reports to the President and the management team as needed. The Compliance Officer also



periodically reviews and revises the compliance program to respond to changes in the company's needs, applicable laws and regulations, and best practices in the industry. Additionally, Shionogi has established a Compliance Committee to provide leadership, assist in the development and implementation of the CCP. The Compliance Committee is chaired by the Compliance Officer and its membership consists of senior management.

Education and Training

Shionogi provides regular education and training for all employees (e.g., officers, directors, managers, etc.) regarding the CCP. Shionogi also provide more specific education and training to employees who interact with healthcare practitioners, employees who are involved in the sale and marketing of pharmaceutical products, and employees who are in a position to prevent and reduce the risk of fraud and abuse in federal and state health care programs. This additional education and training includes, but is not limited to, training on Company policies and procedures which are consistent with the PhRMA Code, the OIG Guidance, anti-kickback statutes, laws and regulations governing the advertising and promotion of pharmaceutical products, Prescription Drug Marketing Act among others. The Company will review and update its training programs periodically, as well as identify additional areas of training on an ongoing basis.

Effective Lines of Communication

Shionogi has established and implemented avenues, including but not limited to the Alert Line, for reporting general issues, allegations of suspected misconduct, and/or to raise compliance concerns. In addition, Shionogi has an open door, anti-retaliation, policy to encourage and protect employees who raise issues, concerns, problems and suggestions with their immediate supervisor or other manager without fear of retaliation and with the assurance that the matter will be protected from improper dissemination or disclosure.

Reporting, Investigating, and Responding to Violations

It is the obligation of every Shionogi employee to immediately report any violations or suspected violations of the law, regulations or Shionogi's compliance program to the employee's manager, the Compliance Officer or the Alert Line. Reports made through the Alert Line may be made anonymously and confidentially. The Alert Line telephone number is **1-800-792-8117**.

Shionogi does not permit retaliation of any kind against employees for good faith reports of misconduct or ethical violations or for participating in any investigation. Moreover, all reported violations of this Comprehensive Compliance Program will be promptly investigated by the Compliance Office or an appropriate designee. Confirmed violations shall be promptly addressed appropriately, including disciplinary action or termination of employees.



Auditing and Monitoring

Shionogi uses audits and other evaluation techniques to monitor compliance, identify problem areas, and assist in the reduction of identified problems. The goal of these audits is to ensure (i) that Shionogi has adequate policies in place covering identified risk areas, (ii) that the policies have been effectively implemented and communicated, and (iii) that the polices are being followed. Such auditing and monitoring takes place under the direction of the Compliance Office.

Discipline for Violations

When compliance violations by Company employees, consultants, or agents have been confirmed, appropriate disciplinary action is taken. The specific disciplinary action for misconduct varies depending upon the situation, but ranges from verbal warnings to suspension and termination. Each situation is evaluated by the employee's supervisor, the Human Resources Department, and/or the company's Compliance Office, taking into account all relevant factors.

Hiring

Shionogi is committed to hiring a workforce that maintains a high degree of integrity, accountability, teamwork, business results and a work-life balance in order to achieve professional as well as overall Company goals. Shionogi requires that all employees are qualified and skilled for the position attained. All prospective and/or current Company employees undergoing a drug screening and a background check to ensure the person has not been convicted of a criminal offense that falls within the scope of 42 U.S.C. §1320a-7(a). Prospective and Company employees, agents and consultants are also screened to ensure that they are not excluded, debarred, suspended, or otherwise ineligible to participate in any federal or state healthcare program, procurement or nonprocurement program.

Spending Limit

In addition to the requirements set out in the PhRMA Code, Shionogi has established an aggregate annual spending limit of \$1,500 on meals and educational items which may be provided to a health care professional. Fees for services to health care professionals are not included in this amount, but such fees are based on fair market value for the services. Prescription product samples intended for free distribution to patients' financial support for continuing education programs and financial support for health educational scholarships are exempt from the limit.