

CHIESI USA, INC.
COMPREHENSIVE COMPLIANCE PROGRAM
May 1, 2015

Chiesi USA, Inc. (the “**Company**”) is committed to compliance with the full range of laws, regulations and policies governing the marketing and promotion of its pharmaceutical products. Accordingly, the Company has established this Comprehensive Compliance Program (the “**CCP**”). The CCP incorporates recommendations of (i) the “Compliance Program Guidance for Pharmaceutical Manufacturers,” published by the Office of the Inspector General (“**OIG**”) of the United States Department of Health and Human Services (the “**CPG**”); (ii) United States Department of Health and Human Services; and, (iii) the Pharmaceutical Research and Manufacturers Association (“**PhRMA**”) “Code of Interactions with Healthcare Professionals” (“**PhRMA Code**”). All Company employees involved in sales, marketing, price reporting, medical affairs or those who interact with healthcare providers are expected to be familiar with and adhere to the CCP. Appropriate disciplinary action, up to and including termination, may be taken against any employee whose conduct violates the CCP or applicable laws and regulations. This CCP is intended to comply with California Health & Safety Code § 119400 et seq.

The Company’s CCP consists of the following elements:

- Written Policies and Procedures. The Company has developed a written Code of Business Conduct and Ethics (the “**Code**”) and a Compliance Program for Promotional and Marketing Activities (the “**Policies**”) addressing the specific risk areas identified in the CPG. The Policies are designed to provide guidance for the Company’s marketing and sales activities as well as financial arrangements with customers and potential customers. Among other things, the Policies incorporate the guidelines in the PhRMA Code. Chiesi’s directors, officers and employees are expected to comply with the Code, the Policies and all other written policies and procedures.

- Compliance Personnel. The Company’s Board of Directors designates the Company’s compliance officer (the “**Compliance Officer**”) and compliance chairperson (the “**Compliance Chairperson**”), collectively “**Compliance**

Leadership". The Compliance Officer reports directly to the Chief Executive Officer, the Global Compliance Officer and/or to the Board of Directors, as deemed appropriate. The Compliance Chairperson reports directly to the Compliance Officer, the Global Compliance Officer and/or the Board of Directors. Compliance Leadership has the ability to effectuate change within the organization as necessary and to exercise independent judgment. The compliance function has unrestricted access to information, executives and meetings related to business operations. In addition, the Company has established a Compliance Committee. The membership of the Company's Compliance Committee includes (i) the Compliance Officer, (ii) the Compliance Chairperson; and, (iii) representatives from the Functional departments of the Company.

- Employee Training. An important element of the CCP is educating and training all employees and applicable consultants, contractors and interns about their legal and ethical obligations under the CCP and all other applicable laws, regulations and Company policies. As a condition of new or employment at the Company, all employees must receive such training as part of the new hire orientation, and existing personnel must receive compliance training at least on an annual basis. . The Company may require additional Compliance Training as it deems necessary (for example, when problems are detected or when compliance-related policies are revised). In addition, the Company reviews and updates its training programs periodically and identifies additional areas for training on an ongoing basis.
- Lines of communication. The Company has developed effective lines of communication for Company personnel to report problems and ask questions regarding the CCP, the Policies or other compliance issues. Employees may bring any workplace matter, including questions about ethical situations or specific conduct and reports of potential violations of laws, regulations, or Company policies, to the attention of management without fear of retaliation or retribution. The Company expects every employee to promptly alert any suspected violation of, or questions regarding, the CCP and the Policies to his or her supervisor, the Compliance Officer, the Compliance Chairperson or

Human Resources. Employees may also report potential violation son an anonymous basis by calling the Company’s corporate governance hotline at 1 (800) 799-6158.

- Internal Review, Monitoring and Auditing. Compliance Leadership is charged with developing plans to audit and monitor compliance in accordance with Chiesi’s policies, procedures and applicable laws and regulations. These audits are intended to identify potential or existing areas of concern and inform corrective actions designed to prevent the recurrence of non-compliance. The nature, frequency, and extent of compliance auditing and monitoring varies depending on a number of factors, including new regulatory requirements, changes in business practices and other factors. The Company has committees in place to review, monitor and audit certain activities such as grants, promotional materials, meals with healthcare providers and other activities cited in the CCP. Additionally, “for cause” audits and reviews are undertaken as appropriate.
- Enforcement. All Chiesi employees, including management and the Board of Directors, are expected to be familiar with and adhere to the CCP, the Code, the Policies and other applicable laws and regulations. Appropriate disciplinary action, up to and including termination, may be taken against any employee who fails to adhere to these policies.
- Investigative and Corrective Action. All reported violations and detected problems of the fraud and abuse laws, the Code, the CCP or of the Policies are investigated by Compliance Leadership and responded to promptly. If corrective action by the Company is required, it is undertaken promptly.

Chiesi will assess its Comprehensive Compliance Program at least annually.

Copies of the CCP and the State of California Compliance Declaration may be obtained by calling 1 (800) 799-6158.