

CHIESI USA, INC.

State of California Compliance Program Declaration

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 of the United States Department of Health and Human Services; (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.

Under the continuing commitment to compliance with all applicable laws and regulations, the Company declares that, to the best of its knowledge and based on a good faith understanding of the statutory requirements, Chiesi’s Comprehensive Compliance Program is consistent with California Health & Safety Code § 119400 – 119402. As of the date of this declaration, the Company believes it is in compliance with all compliance policies outlines above in all material respects.

In order to comply with California Health & Safety Code § 119402, , the Company has set an annual spending limit on educational items and promotional activities or items or activities that the company may lawfully give or otherwise provide to a healthcare professional located in California, subject to permitted exclusions, at \$2,500 per healthcare professional. The annual limit is not intended to serve as a spending objective or goal by the Company for all healthcare professionals in California. Rather, it is intended to establish an annual upper limit for the healthcare professionals with whom Company personnel interact. Chiesi will assess the spend limit on at least an annual

basis and will identify and adjust the Program to meet any operational or practical issues related to complying with this new requirement as well as any new legislative requirements.

Chiesi exempts certain expenditures from this limit based upon a good faith understanding of California Health & Safety Code §§ 119400-119402 and the PhRMA Code. Such exemptions include:

- Drug samples given to physicians and healthcare professionals intended for free distribution to patients;
- Financial support for continuing medical education forums;
- Financial support for health educational scholarships;
- Payments made for legitimate professional services provided by a healthcare or medical professional that are provided at the fair market value for the services rendered; and,
- Documents, informational or educational brochures, and other items that inform medical or healthcare professional about Chiesi products, provide scientific and educational data, support medical research and education, or enhance a patient's understanding or management of a disease state or disorder.

This program became effective as of October 30, 2008 and was last reviewed June 2015. Chiesi will assess its Comprehensive Compliance Program at least annually.

Copies of this declaration and the CCP may be obtained by calling 1 (800) 799-6158.