

Merz North America, Inc.

CALIFORNIA COMPREHENSIVE COMPLIANCE PROGRAM AND DECLARATION PURSUANT TO CAL. HEALTH & SAFETY CODE §§ 119400-119402

INTRODUCTION

Merz North America, Inc. (“Merz”) is committed to conducting business with uncompromising integrity and the highest levels of business ethics. Merz has established a comprehensive compliance program in accordance with the Compliance Program Guidance published by the Office of Inspector General, U.S. Department of Health and Human Services (“HHS-OIG Guidance”). To the best of our knowledge and belief and based on our good faith understanding of the law, our compliance program meets the requirements of Cal. Health and Safety Code §§ 119400-119402. Consistent with the HHS-OIG Guidance, we have tailored our compliance program to the size, organizational structure, resources, and nature of our medical device business. Although the statute references compliance with the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals (the “PhRMA Code”), Merz’s compliance program has been developed in accordance with the AdvaMed Code of Ethics on Interactions with Healthcare Professionals (“AdvaMed Code”) which is substantially similar to the PhRMA Code while taking into account the uniqueness of interactions between medical device manufacturers and healthcare professionals. The purpose of our compliance program is to prevent and detect violations of law or company policy. As the HHS-OIG Guidance recognizes, however, the implementation of such a program cannot guarantee the elimination of improper conduct. It is Merz’s expectation that all employees will comply with our compliance program as well as with all applicable laws, regulations, and policies. We continuously review, assess, and improve our compliance program to meet changing needs and circumstances.

COMPLIANCE PROGRAM OVERVIEW

1. **Written Policies and Procedures:** Merz has adopted a series of policies and procedures in furtherance of its commitment to the highest standards of business ethics, including a US Healthcare Compliance Code that incorporates the AdvaMed Code and helps to ensure Merz complies with all relevant healthcare compliance laws, regulations, and codes.
2. **Leadership and Oversight:** Merz’s compliance program is overseen by the Chief Compliance Officer with input from executive management through the Compliance Committee and is operated and monitored by experienced regional and functional compliance professionals.

3. **Training and Education:** Merz provides comprehensive training (online and live) on its Standards of Business Conduct as well as training to relevant audiences on healthcare compliance, anti-corruption, privacy, and related subjects.
4. **Communication Lines:** Merz has an open-door policy that allows employees to report their concerns to any level of management. Employees are encouraged to communicate their compliance concerns to their direct managers but are also invited to share their concerns with other resources, including but not limited to, Human Resources, Legal, or Compliance, or via the Compliance Hotline which allows for anonymous reporting of compliance concerns. Merz adheres to a zero tolerance non-retaliation policy.
5. **Auditing and Monitoring:** On a routine basis, Merz conducts internal audits, risk assessments and targeted monitoring activities to identify potential issues, control gaps and opportunities for improvements to policies, procedures and processes.
6. **Disciplinary Action:** Merz has implemented processes for addressing compliance violations, and employees are aware that failures to comply with Merz policies, procedures and ethical standards can lead to disciplinary action up to and including termination.
7. **Investigation and Corrective Action:** All reported compliance concerns are investigated objectively, fairly and promptly. Where appropriate, corrective action plans are implemented to remediate or improve existing policies, procedures, and processes. Such correction actions may include disciplinary action in situations involving employee misconduct.

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