

OSMOTICA PHARMACEUTICALS COMPLIANCE PROGRAM OVERVIEW

I. INTRODUCTION

Osmotica Pharmaceuticals plc and its subsidiaries and affiliates (“Osmotica”) is committed to establishing and maintaining an effective compliance program in accordance with “Compliance Program Guidance for Pharmaceutical Manufacturers,” published by the Office of Inspector General, U.S. Department of Health and Human Services (the “OIG Guidance”). Our Compliance Program is one of the key components of our commitment to the highest standards of corporate conduct.

The purpose of our Compliance Program is to prevent and detect violations of law or company policy. As the OIG Guidance recognizes, however, the implementation of such a program cannot guarantee that improper employee conduct will be entirely eliminated. Nonetheless, it is Osmotica’s expectation that employees will comply with our Code of Business Conduct and Ethics, and the policies established in support of our Code. In the event that Osmotica becomes aware of violations of law or company policy, we will investigate the matter and, where appropriate, take disciplinary action and implement corrective measures to prevent future violations.

Osmotica has described below the fundamental elements of our Corporate Compliance Program. As OIG calls for in its OIG Guidance, we have tailored our Compliance Program to fit the unique environment of our company. Moreover, our Compliance Program is dynamic; we regularly review and enhance our Compliance Program to meet our evolving compliance needs.

II. Overview of Compliance Program

1. Leadership and Structure.

- **Compliance Officer.** We have designated a senior-level official to serve as our corporate Compliance Officer. We are committed to ensuring that the Compliance Officer has the ability to effectuate change within the organization as necessary and to exercise independent judgment. The Compliance Officer is charged with the responsibility for developing, operating and monitoring the Compliance Program.
- **Compliance Committee.** Osmotica has established a Compliance Committee to advise the Compliance Officer and assist in the implementation of the Compliance Program.

2. Written standards.

- Osmotica’s Code of Business Conduct and Ethics is our statement of ethical and compliance principles that guide our daily operations. The Code establishes that we expect management, employees, and agents of the company to act in accordance with law and applicable company policy. The Code articulates our fundamental principles, values and framework for action within our organization.

- The OIG Guidance has identified several potential risk areas for pharmaceutical manufacturers, and called on companies to develop compliance policies in these risk areas. These risk areas are (1) data integrity pertaining to government reimbursement practices; (2) kickbacks and other illegal remuneration; and (3) compliance with laws regulating drug samples.
3. **Education and Training.** A critical element of our Compliance Program is the education and training of our employees on their legal and ethical obligations under applicable federal health care program requirements. Osmotica is committed to taking all necessary steps to effectively communicate our standards and procedures to all affected personnel. Moreover, Osmotica will regularly review and update its training programs, as well as identify additional areas of training on an “as needed” basis.
 4. **Internal Lines of Communication.** Osmotica is committed to fostering dialogue between management and employees. Our goal is that all employees, when seeking answers to questions or reporting potential instances of fraud and abuse, should know who to turn to for a meaningful response and should be able to do so without fear of retribution.
 5. **Auditing and Monitoring.** Osmotica’s Compliance Program includes efforts to monitor, audit, and evaluate compliance with the company’s compliance policies and procedures. We note that in accordance with the OIG Guidance, the nature of our reviews as well as the extent and frequency of our compliance monitoring and auditing varies according to a variety of factors, including new regulatory requirements, changes in business practices, and other considerations.
 6. **Responding to Potential Violations.** Although each situation is considered on a case-by-case basis, we will consistently undertake appropriate disciplinary action to address inappropriate conduct and deter future violations.
 7. **Corrective Action Procedures.** A Compliance Program increases the likelihood of preventing, or at least identifying unlawful and unethical behavior. However, the OIG recognizes that even an effective Compliance Program may not prevent all violations. As such, our compliance program requires the company to respond promptly to potential violations of law or company policy, take appropriate disciplinary action, assess whether the violation is in part due to gaps in our policies, practices, or internal controls, and take action to prevent future violations.

**CALIFORNIA
ANNUAL DECLARATION OF COMPLIANCE**

Osmotica Pharmaceuticals, and its subsidiaries and affiliates (“Osmotica”) is committed to conducting its business ethically and in accordance with all applicable laws. We have developed a comprehensive compliance program (CCP) in accordance with California Health and Safety Code sections 119400 and 119402. The CCP is consistent with both the April 2003 *Compliance Program Guidance for Pharmaceutical Manufacturers* published by the Office of Inspector General of the U.S. Department of Health and Human Services and the Pharmaceutical Research and Manufacturers of America (PhRMA) *Code on Interactions with Health Care Professionals*. Osmotica has set the annual aggregate limit on covered promotional expenditures at \$2000.00 per covered California medical or healthcare professional. This limit may be revised by Osmotica from time to time.

To the best of our knowledge and based on our good faith understanding of the statutory requirements of this California law, we are, in all material respects, in compliance with the CCP and these statutory requirements.

The Office of the Inspector General has recognized in the *Compliance Program Guidance for Pharmaceutical Manufacturers* that the implementation of an effective compliance program cannot entirely eliminate the chance of improper conduct. Osmotica’s CCP is reasonably designed with the goal of preventing, detecting, and addressing improper conduct. In the event Osmotica becomes aware of potential violations of law or Company policy, Osmotica will, where appropriate, investigate the matter, take disciplinary action, and/or implement corrective measures to prevent future violations. This description of our Compliance Program reflects the plan we have implemented. We will periodically reassess the program to improve it, and may refine the elements as necessary. Osmotica is committed to upholding the highest standards of business conduct and ethics in its relationships with customers, employees, shareholders, the business community, and state and federal governments.

If you would like to receive copies of this Declaration and Osmotica’s Comprehensive Compliance Program, you may call Osmotica Pharmaceuticals’ Compliance Officer at 908-809-1351 or email at compliance@osmotica.com and request printed copies.

Dated: September 14, 2018