



## **UCB COMPLIANCE PROGRAM**

### **Declaration of Compliance**

#### **I. INTRODUCTION**

As part of UCB's continued efforts in the area of compliance, we have developed a Comprehensive Compliance Program, as required by California law.

To the best of our knowledge, and based on our good faith understanding of the statutory requirements, we have established a Comprehensive Compliance Program (CCP) compliant with the requirements of Cal. Health and Safety Code §§ 119400-119402. We have developed a CCP that is tailored to the size, organizational structure, and resources of the company, and has been implemented to meet the compliance goals set forth by the state of California. The description of our CCP, provided below, reflects the plan we have implemented to comply with California law. To our knowledge, we are, in all material respects, in compliance with our CCP as described, meaning that we have established the elements outlined.

#### **II. OVERVIEW OF COMPLIANCE PROGRAM**

##### **1. Leadership and Structure.**

- **Compliance Officer.** We have designated a senior-level official to serve as our Compliance Officer. This senior-level official works in close association with the company's legal department and outside legal counsel, to develop, operate and monitor the Compliance Program. The Compliance Officer reports to the President of UCB and periodically makes reports to UCB leadership on the progress and status of the company's Compliance Program.

##### **2. Written standards.**

- The HHS-OIG Guidance has identified several potential risk areas for pharmaceutical manufacturers, and has called on companies to develop compliance standard operating procedures 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. UCB has adopted standard operating procedures to address these risk areas. UCB also has adopted standard operating procedures to implement the PhRMA Code on Interactions with Health Care Professionals.



- We also have established spending limits for certain promotional activities directed toward healthcare professionals in California. The limit we have established for this year is \$1700.

- 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 laws and company policies, including federal health care program requirements. UCB is committed to taking all necessary steps to effectively communicate our standards and procedures to all affected personnel. Moreover UCB will regularly review and update its training programs, as well as identify additional areas of training on an “as needed” basis. UCB requires compliance training for all new hires and annual training for existing employees. This training is tailored to the employees’ job functions when necessary.
- 4. Internal Lines of Communication.** UCB 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. To that end, we have adopted open-door policies, as well as confidentiality and non-retaliation policies. UCB also utilizes a hotline number to ensure that employees have a confidential, anonymous means of reporting compliance issues.
- 5. Auditing and Monitoring.** UCB’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 HHS-OIG Guidance, the nature of our reviews as well as the extent and frequency of our compliance monitoring and auditing vary according to a variety of factors, including new regulatory requirements, changes in business practices, and other considerations. The areas to be audited are selected by the Compliance Officer and audits are conducted by the Compliance Officer based on the relative degree of risk identified by a risk assessment and ongoing monitoring of the risk areas.
- 6. Responding to Potential Violations.** UCB’s Compliance Program includes clear disciplinary policies that set out the consequences of violating the law, company policy, or standard operating procedures. Our policies provide for sanctions that are appropriate to the severity of the violation, and to deter future violations. In addition, UCB screens employees against the HHS OIG and GSA exclusion/debarment lists.
- 7. Corrective Action Procedures.** A Compliance Program increases the likelihood of preventing, or at least identifying, unlawful and unethical behavior. However, HHS-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. UCB has implemented a policy that governs the conduct of investigations. .

### **III. CHANGES TO CCP AND DECLARATION**

Recognizing that compliance is a dynamic concept that must be adapted to the characteristics of a particular company, we are continually reassessing our program and will continue to refine these compliance elements, as necessary.

By making this declaration, we are not asserting that we can prevent individual employees from improper conduct. As of the date of this statement, the above referenced systems are in place, and these systems will be reassessed on an annual basis.