

## **BRECKENRIDGE PHARMACEUTICAL, INC. COMPREHENSIVE COMPLIANCE PROGRAM**

### **A. General**

Breckenridge Pharmaceutical, Inc. (“BPI”) is committed to the highest possible standards of ethical, moral and legal business conduct. This Comprehensive Compliance Program (“CCP”) is a summary of BPI’s compliance program and does not summarize all laws and regulations applicable to BPI and its employees, officers, directors and vendors. The standards enumerated below are embodied in BPI’s Code of Ethics.

### **B. Interactions with Healthcare Professionals**

BPI’s CCP was established in accordance with the Office of Inspector General’s Compliance Program Guidance for Pharmaceutical Manufacturers (“OIG CPG”) and the Pharmaceutical Research Manufacturers of America’s Code on Interactions with Healthcare Professionals (“PhRMA Code”) dated January 2022. BPI employees, officers, directors and vendors are expected to interact with healthcare providers in compliance with this CCP (including the OIG CPG and PhRMA Code), BPI’s Code of Ethics and compliance policies and procedures, and such other applicable laws, regulations and guidelines.

BPI’s CCP provides BPI representatives with guidance regarding interactions with healthcare providers and healthcare entities including, but not limited to: advisory boards, speaker programs, gifts, educational items, grants, informational lunches, physician consulting and advisory arrangements, and BPI promotional materials, as applicable. Members of the sales and commercial operations department each receive BPI’s Code of Ethics, which includes additional compliance guidance.

### **C. Compliance Officer**

BPI has a Corporate Compliance Officer (Head of Compliance) who reports directly to BPI’s President. The Corporate Compliance Officer’s primary responsibilities include, but are not limited to: (i) oversight of CCP day-to-day operations; (ii) developing and implementing policies, procedures and practices to implement and administer the CCP; (iii) assessing, developing and implementing BPI’s compliance training activities, including dissemination of guidelines and well-publicized policies and disciplinary guidelines; (iv) monitoring BPI’s Compliance Hotline and responding as appropriate; (v) investigating compliance matters, including recommendations and oversight of any required disciplinary or other corrective actions; and (vi) establishing and executing adequate auditing and monitoring processes to assure adherence with the CCP.

## **D. Training and Education**

BPI's Code of Ethics and relevant job-specific materials are distributed to newly hired employees. Each new hire must agree in writing to comply with BPI's Code of Ethics. All BPI employees are formally trained in an introductory CCP training and must sign a verification of participation in this session. Follow-up training is provided at least annually to all employees who have sales and marketing responsibilities via employee meetings, videoconference or email. Follow-up training includes periodic updates to the Code of Ethics and supplemental compliance materials. Such training is documented by the signing of an acknowledgement form.

## **E. Lines of Communication**

BPI employees are encouraged to openly communicate compliance issues and concerns in a prompt manner. Employees are instructed that any actual or perceived communication problem should be reported to their supervisors, the HR Department, the Head of Compliance or the Legal Department. No retaliation will be taken against any employee for raising concerns or issues of legal, regulatory or policy compliance. The taking of any such retaliation by any employee, officer or director is grounds for disciplinary action.

BPI operates an anonymous toll-free Compliance Hotline administered by a third-party vendor to help ensure compliance violations are properly reported and thoroughly investigated. The Hotline promotes a culture of adherence to ethical business practices related to the sales, marketing and contracting of BPI products and to provide the tools with which to do so. Calls to the Compliance Hotline are answered by trained personnel and monitored daily. Calls may be made on an anonymous and confidential basis. Information from each call will be forwarded to the appropriate BPI office for follow-up, depending on the nature of the issue or concern raised. All calls are otherwise kept confidential to the extent permitted by law. All reports of improper conduct will be reviewed and investigated and action will be taken as appropriate.

- (844) 920-1212

## **F. Auditing and Monitoring**

The Head of Compliance in conjunction with the Compliance Manager of Towa Pharma International Holdings, S.L.U. (BPI's parent company) periodically monitor and audit BPI's activities to ensure CCP compliance. Actions include periodic reviews of financial and other records related to interactions with healthcare professionals, and reporting and monitoring employee training participation. Audit results and corrective actions are periodically reported to executive management.

## **G. Disciplinary Guidelines; Investigation; Corrective Action**

The Head of Compliance, in conjunction with BPI's HR Department as applicable, oversees investigations of compliance-related issues. BPI is committed to responding promptly to non-compliance with CCP or BPI policy and taking appropriate corrective action. Disciplinary actions,

ranging from verbal reprimand, written warning, suspension and termination are determined on a case-by-case basis and are set forth in the Code of Ethics and employee handbooks.

#### **H. Annual Spending Limit**

California law requires pharmaceutical companies to voluntarily adopt a specific annual dollar limit on gifts, promotional materials, or items or activities that the pharmaceutical company and its employees and representatives may give or otherwise provide to an individual medical or health care professional in California. The limit does not include amounts attributable to drug samples, financial support for continuing medical education, or payment for legitimate professional services.

BPI has adopted an annual spending limit of \$1,200. This limit represents a spending cap and BPI anticipates that amounts provided will be substantially less than this maximum amount. The annual limit may be revised from time to time.

#### **I. Availability of Program: Annual Declaration of Compliance**

A copy of this CCP can be downloaded from BPI's website, [www.bpirx.com](http://www.bpirx.com), and is made available to any interested person. In accordance with Section 119402(e) of the California Health & Safety Code, BPI will post an Annual Declaration of Compliance on its website each calendar year. Requests for copies of this CCP and the Annual Declaration of Compliance (upon posting) may be made by calling BPI toll-free at (800) 814-4349.