



## **ALK-ABELLÓ, INC. COMPREHENSIVE COMPLIANCE PROGRAM**

### **A. GENERAL**

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

### **B. INTERACTIONS WITH HEALTHCARE PROFESSIONALS**

ALK’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 July 2002 with revisions effective January 2009 and 2022. ALK employees, officers, directors and vendors are expected to interact with healthcare providers in compliance with this CCP (including the OIG CPG and PhRMA Code), ALK’s Code of Conduct and compliance policies and procedures, and such other applicable laws, regulations and guidelines.

ALK’s CCP provides ALK 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 ALK promotional materials. Members of the commercial operations department each receive ALK’s Code of Conduct, which includes additional compliance guidance.

### **C. COMPLIANCE OFFICER; COMPLIANCE COMMITTEE**

ALK has a Corporate Compliance Officer (CCO) who reports to the Sr. Vice President Americas Commercial Operations and also to the Vice President, Corporate Affairs and Global Business Support. The Corporate Compliance Officer’s primary responsibilities, in conjunction with ALK’s Corporate Compliance Committee as applicable, 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 ALK’s compliance training activities, including dissemination of guidelines and well-publicized policies and disciplinary guidelines; (iv) monitoring ALK’s Compliance Alertline 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. In the event the CCO role is open, the duties and responsibilities assigned to this role will be reassigned to a qualified individual by their management.

### **D. TRAINING AND EDUCATION**

ALK’s Code of Conduct and relevant job-specific materials are distributed to newly hired employees engaged in sales and commercial operations. Each new hire must agree in writing to comply with ALK’s Code of Conduct. All ALK 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 Conduct and supplemental compliance materials. Such training is documented by the signing of an acknowledgement form.



## **E. LINES OF COMMUNICATION**

ALK 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 Corporate Compliance Officer or the Legal Department. Not 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.

ALK operates an anonymous toll-free Compliance Alertline administered by a third-party vendor to help ensure compliance violations are properly reported and thoroughly investigated. The Alertline promotes a culture of adherence to ethical business practices related to the sales, marketing and contracting of ALK promoted products and to provide the tools with which to do so. Calls to the Compliance Alertline 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 ALK 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.

- (855) 363-0859

## **F. AUDITING AND MONITORING**

The Corporate Compliance Officer in conjunction with ALK's Corporate Compliance Committee periodically monitor and audit ALK'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 Corporate Compliance Officer in conjunction with ALK's HR Department as applicable, oversees investigations of compliance-related issues. ALK is committed to responding promptly to non-compliance with CCP or ALK policy and taking appropriate corrective action. Disciplinary actions, ranging from verbal reprimand, written warning and termination are determined on a case-by-case basis and are set forth in the Code of Conduct 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 healthcare 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.

ALK has adopted an annual spending limit of \$1,200. This limit represents a spending cap and ALK anticipated 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 the CCP can be downloaded from ALK's website, [www.alk.net/us](http://www.alk.net/us), and is made available to any interested person. In accordance with Section 119402(e) of the California Health & Safety Code, ALK will post an Annual Declaration of Compliance on its website each calendar year. Requests for copies of the CCP and the Annual Declaration of Compliance (upon posting) may be made by calling ALK toll-free at (800) 325-7354.