



# Policies for California's Comprehensive Compliance Program

## Introduction

As a pharmaceutical manufacturer, Alexion Pharmaceuticals, Inc., and its subsidiaries ("Alexion") conduct a wide array of activities in the health care marketplace, including research, medical and other education, marketing, and sales. Each of these activities is subject to numerous legal and ethical standards, many of which are unique to the healthcare industry. Alexion is committed to complying with all applicable laws and regulations in its marketing, promotional, educational, and research activities. Specifically, and for the purposes of complying with the State of California's requirement that pharmaceutical companies implement and maintain a comprehensive Compliance Program concerning the sales and marketing of its products, Alexion has in place a Compliance Program that includes a series of policies entitled "Policies for Interactions with Customers" ("Compliance Policies") and periodic training for affected employees interacting with customers ("Employees"). This program is consistent with the April 2003 publication developed by the United States Department of Health and Human Services Office of Inspector General ("OIG") entitled "Compliance Program Guidance for Pharmaceutical Manufacturers" and the July 2002 document "Code on Interactions with Health Care Professionals" ("PhRMA Code") developed by the Pharmaceutical Research and Manufacturers of America ("PhRMA") with revisions effective January 1, 2009. Alexion's Compliance Policies include, among other things, specific policies placing limits on gifts to healthcare practitioners, policies addressing consultants, speakers and speaker training, and product support services, and policies establishing committees for the review of promotional material, educational information, and grants.

## **A. Overview of Program Standards**

Alexion's promotional, educational, and clinical arrangements with customers are subject to the requirements of a variety of legal and ethical rules. The Company is committed to conducting its affairs in compliance with these standards.

The Department of Health and Human Services Office of the Inspector General's guidance to the pharmaceutical industry on designing and implementing voluntary compliance programs includes seven elements for an effective compliance program. Alexion has tailored its Compliance Program to meet these voluntary standards. They are:

### **1. Implementing written policies and procedures**

As part of its Compliance Program, Alexion has written and communicated policies and procedures to all Employees interacting with customers. These policies and procedures are provided to all affected Employees when first employed and are available electronically through Alexion's Compliance Officer.

### **2. Designating a compliance officer and compliance committee**

Alexion has designated a Compliance Officer who is responsible for ensuring that employees adhere to the Compliance Policies. The Compliance Officer also will ensure that the Comprehensive Compliance Program is maintained and that the program is consistent with the State of California's Compliance Plan Law (Cal Health and Safety Code §119400 et. seq.). In addition, a Compliance Committee has been established. Members of the committee will meet on an ad hoc basis to review policies and procedures, resolve compliance issues and serve as a body to review complaints or questions. This committee will include as members Alexion's Compliance Officer, a representative of Human Resources and other members of executive management.

### **3. Conducting effective training and education**

Alexion has distributed the Compliance Policies to all affected Employees. Training is conducted for new Employees during employee orientation and is repeated at appropriate times during the year. Employees sign an acknowledgement after the receipt of the Policies. Copies of the acknowledgement are retained by the Company.

### **4. Developing effective lines of communication**

During training sessions, Alexion Employees have an open line of communication with Alexion's Compliance Officer. In addition, under Alexion's Compliance Policies, employees are provided a mechanism to communicate with Alexion management and the Compliance Officer and also are provided an anonymous method of communication through a hotline. The hotline is available through the Company's toll-free number (866) 551-3627.

### **5. Conducting internal monitoring and auditing**

Through training updates and testing procedures, training is continually monitored. Auditing is performed on a periodic basis by Alexion's internal audit group. A member of Alexion's internal audit group will advise the Compliance Committee on auditing procedures and audit results.

6. **Enforcing standards through well-publicized disciplinary guidelines**

Alexion's Compliance Policies include a clear description of disciplinary standards. Also, all disciplinary matters are presented to the Compliance Committee for review. The Compliance Policies are disseminated to all affected Employees.

7. **Responding promptly to potential instances of noncompliance and undertaking corrective action**

Under Alexion's Compliance Policies, all incidents requiring investigation will be addressed promptly and presented to the Compliance Committee. Any corrective action will take place in a timely fashion to ensure that the incident is resolved. Several methods of bringing incidents to the attention of the company are included in the Compliance Policies, including an anonymous Compliance Hotline.

**B. Compliance Officer and Annual Declaration of Compliance for Purposes of California Health & Safety Codes §§ 119400-119402**

For the purposes of the State of California's Comprehensive Compliance Plan Law, Alexion has designated a Compliance Officer. Alexion has in place a Comprehensive Compliance Program that is consistent with California's Compliance Plan Law. The Program is also consistent with the April 2003 publication developed by the United

States Department of Health and Human Services Office of Inspector General ("OIG") entitled "Compliance Program Guidance for Pharmaceutical Manufacturers" and the July 2002 document "Code on Interactions with Health Care Professionals" ("PhRMA Code") developed by the Pharmaceutical Research and Manufacturers of America ("PhRMA") with revisions effective January 1, 2009. **This document and declaration is available on Alexion's website at [www.alexionpharm.com](http://www.alexionpharm.com) and also through the Company's toll-free number (866) 551-3627.**