



# Comprehensive Compliance Program

## **Overview**

Novalar Pharmaceuticals Inc. (“Novalar”) has established a Comprehensive Compliance Program pursuant to California Health & Safety Code Sections 119400-119402, (“California Compliance Law”). Novalar’s Comprehensive Compliance Program consists of the following fundamental elements.

## **Responsibilities and Oversight**

Novalar has created a Commercial Compliance Committee responsible for the oversight, implementation, and monitoring of the Compliance Program. Novalar has designated a Commercial Compliance Officer with responsibility for oversight and implementation of the Comprehensive Compliance Program and commercial compliance matters. The Commercial Compliance Officer reports directly to the President and Chief Executive Officer in matters of compliance.

## **Policies and Procedures**

Novalar has developed written policies for specific areas of compliance and interactions with healthcare professionals. These policies include the following:

- Sales to customers;
- Review and distribution of promotional material;
- Support of investigator-initiated studies;
- Promotional speaker program;
- Exhibits and scientific booths;
- Educational grant program;

- Consultancy and Advisory Boards

### **Annual Limit for Spending on Promotional Items and Activities**

Novalar has established an annual aggregate limit for spending on promotional items and activities provided to individual medical or healthcare professionals in California of \$2,000 per individual medical or healthcare professional. This amount represents a spending maximum and does not represent an average or a spending goal. This limit may be revised from time to time, in which case the revised limit will be provided in this section of Novalar's website. The annual limit does not include the following:

- Drug samples given to physicians and healthcare professionals intended for free distribution to patients;
- Financial support for continuing medical education forums;
- Financial support for health education scholarships;
- Payments for legitimate professional services (e.g., consulting on clinical trial design, acting as an investigator in a clinical trial, serving as a speaker), and meals and other expenses associated with the provision of such services.

## **Education and Training**

Novalar is committed to communicating our standards and procedures to our employees. Employees are trained on our Code of Business Conduct and Ethics, and to our Compliance policies as appropriate.

## **Internal Communications and Reporting of Complaints**

Novalar has developed procedures for employees to report concerns about actual or possible violations of the Compliance Program or applicable laws. Novalar has also developed procedures for evaluating, investigating, and responding to such reports.

## **Annual Declaration**

Novalar operates on a calendar year cycle. Beginning with the close of calendar year 2009, Novalar will post its annual declaration.