

# **NOVOGYNE COMPREHENSIVE COMPLIANCE PROGRAM**

## **I. INTRODUCTION**

Novogyne Pharmaceuticals (Novogyne) is a joint-venture between Novartis Pharmaceuticals Corporation (NPC) and Noven Pharmaceuticals, Inc. (Noven). Novogyne offers pharmaceutical products that enable physicians to better serve the medical needs of mature women. As part of our commitment to deliver value to patients using our products and to conduct business honestly, lawfully, and ethically, Novogyne established and maintains a Comprehensive Compliance Program in accordance with federal, state, and industry regulations and guidelines including the “Compliance Program Guidance for Pharmaceutical Manufacturers,” published by the Office of Inspector General, U.S. Department of Health and Human Services. Novogyne has dedicated significant time and resources to implement a commercial compliance program that represents our commitment to the highest standards of corporate conduct.

Key elements of our Comprehensive Compliance Program include, but are not limited to:

- Extensive policies and procedures that address specific areas of government concern;
- Dedicated compliance oversight functions;
- Multi-faceted training and education programs;
- Multiple compliance communication mechanisms, including an anonymous reporting system dedicated to Novogyne business;
- Targeted compliance monitoring and auditing;
- Published disciplinary guidelines; and
- A protocol for responding promptly to detected problems and implementing corrective action.

## **II. Overview of Novogyne Compliance Program**

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

**Compliance Officer.** Novogyne’s Compliance Officer is provided by Novartis Pharmaceuticals Corporation and is charged with the responsibility for developing, operating, and monitoring the compliance program. The Compliance Officer reports functionally directly to the Management Committee of Novogyne and organizationally to the Vice President of Ethics and Compliance of NPC. Our Compliance Officer has the ability to effectuate change within the organization and to exercise independent judgment.

**Deputy Compliance Officer.** Novogyne’s Deputy Compliance Officer is provided by

Noven Pharmaceuticals, Inc. The Deputy HCC Officer supports and assists the HCC Officer in carrying out his/her role and responsibilities. The Deputy Compliance Officer will act as a liaison between the Compliance Officer and the Noven organization.

**Compliance Committee.** Novogyne has established a Commercial Compliance Committee, which is a cross-functional group of individuals from NPC and Noven whose primary purpose is to assist the Compliance Officer in fulfilling his duty relating to Novogyne's corporate compliance activities. The Committee also acts as an advisory committee to Novogyne's Management Committee. The Commercial Compliance Committee includes representatives from the following departments: Legal Departments, Regulatory, Sales and Marketing, and Compliance.

## ***2. Written Standards.***

Novogyne has developed written compliance policies, procedures, and practices that guide the Company and the conduct of our Associates in day-to-day commercial operations. These policies and procedures have been developed under the direction and supervision of our Compliance Officer, Compliance Committee, Legal Counsel, and management from various functional areas.

**Code of Conduct.** Each company involved in the Novogyne joint-venture has its own respective Code of Conduct. Considering Associates working on Novogyne business retain significant responsibilities from their company of employment, each Novogyne Associate is required to adhere to his or her respective company's Code of Conduct.

**Policies and Procedures.** Novogyne has established policies and procedures to address a variety of potential risk areas, including the potential risk of liability under several fraud and abuse statutes and regulations. These policies and procedures are part of a comprehensive framework of compliance controls that exist throughout various segments of our organization. In particular, Novogyne developed and implemented significant policies and procedures to reduce and eliminate the potential risks identified by the HHS Office of Inspector General in its Compliance Program Guidance for Pharmaceutical Manufacturers and addressed in the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals, including (1) data integrity pertaining to government reimbursement practices, (2) kickbacks and other illegal remuneration, and (3) compliance with laws regulating drug samples.

## ***3. Education and Training.***

Novogyne educates and trains Novogyne Associates on the facets of the Commercial Compliance Program both online at the "Novogyne University" and in live classroom settings. Our education and training covers a variety of laws and regulations that impact the way we conduct business. Our live and computer-based programs include, but are not limited to, meaningful discussion of the application and consequences of the False Claims Act, Anti-Kickback Statute, OIG Compliance Program Guidance, PhRMA Code on Interactions with Healthcare Professionals, as well as other applicable federal, state,

and industry rules and guidelines. Novogyne regularly reviews and updates its training programs, and identifies additional areas of training on an “as needed” basis.

#### ***4. Internal Lines of Communication.***

Novogyne is committed to fostering dialogue between management and associates. Our goal is that all Associates, whether seeking answers to questions or reporting potential instances of fraud and abuse, will 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, confidentiality, and non-retaliation policies.

As part of its commitment to ethical and legal behavior, Novogyne requires its Associates to report any actual or suspected violations of law or ethical standards so that they can be appropriately investigated and addressed. Novogyne Associates can raise legal or ethical concerns in a number of ways including with an appropriate member of Management, through our Human Resources, Legal, or Compliance Departments, or by calling the toll-free, 24-hour, anonymous hotline maintained specifically for Novogyne Associates, contractors, and business partners (888-846-8919).

#### ***5. Auditing and Monitoring.***

Novogyne’s comprehensive compliance program includes activities to monitor, audit, and evaluate compliance with the Company’s policies and procedures. Novogyne’s approach includes targeted monitoring and auditing based on identified and prioritized risk areas. In accordance with the OIG Compliance Program Guidance, the nature of Novogyne’s 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.

#### ***6. Enforcing Standards Through Discipline.***

Any violation of an Associate’s obligations under the Novogyne Commercial Compliance Program can subject an Associate to serious disciplinary measures, including possible termination of employment. An Associate’s obligations include strict observance of all laws and regulations applicable to Novogyne business (e.g., laws and regulations governing the Federal health care programs). Although each situation is considered on a case-by-case basis, Novogyne undertakes significant efforts to ensure consistent and appropriate disciplinary action is taken in response to violations.

#### ***7. Responding to Detected Problems.***

As part of our comprehensive compliance program, Novogyne has established a comprehensive internal investigation and corrective action protocol to ensure that timely, complete, and objective investigations are conducted in response to allegations. In accordance with the OIG Compliance Program Guidance, the exact nature and level of

thoroughness of the internal investigation will vary according to the circumstances. Upon conclusion of an internal investigation, corrective action and preventative measures are determined and implemented as appropriate.

### **III. CLOSING**

Novogyne is dedicated to the maintenance and ongoing assessment required of an effective comprehensive compliance program.

#### **California Health and Safety Code §119402**

Novogyne's relationships with healthcare professionals are intended to benefit patients and to enhance the practice of medicine. Informational presentations and discussions by Company representatives and others speaking on behalf of Novogyne provide valuable scientific and educational benefits. In conjunction with such presentations and discussions, Novogyne employees may offer occasional meals and educational items in accordance with the PhRMA Code on Interactions with Healthcare Professionals.

The California Health and Safety Code §119402 requires pharmaceutical companies to maintain comprehensive compliance programs (CCPs) relating to their interactions with health care professionals (HCPs) as above, and to:

- Establish in its CCP "a specific annual dollar limit on gifts, promotional materials, or items or activities that the pharmaceutical company may give or otherwise provide to a health care professional (see below);"
- Make an annual written declaration that it is in compliance with its CCP and the law (see below);
- Make its compliance program and its annual declaration of compliance available to the public on its website as is done here; and
- Provide a toll-free number to obtain a copy of the CCP and the annual written declaration. That number is 888-253-5099.

Novogyne has declared a specific annual dollar limit of \$1500 per medical or healthcare professional (HCP) in California for educational items and activities in accordance with the PhRMA Code. Novogyne expects that few, if any, California HCPs will approach this limit. Consistent with pharmaceutical marketing laws in other states, in-office food or beverage provided on an occasional basis for \$25 or less per HCP will not be included in Novogyne's annual dollar limit. This spending limit is set by Novogyne and revisited at least annually.

### **California: Novogyne Declaration of Compliance**

**Novogyne Pharmaceuticals  
Declaration of Compliance – June 2009**

**July 1, 2008 - June 30, 2009**

To the best of our knowledge, as of June 30, 2009, Novogyne is in material compliance with its Comprehensive Compliance Program and the requirements of the California Health & Safety Code. It is Novogyne's expectation that all employees and contractors comply with its CCP and all policies that support this program. Novogyne is committed to assessing ongoing compliance with the CCP, which is designed to prevent, detect and address potential or actual instances of non-compliance.