

# **COMPREHENSIVE COMPLIANCE PROGRAM**

## **I. Introduction**

In 2000, Merck & Co., Inc and Schering-Plough Corporation formed a partnership, referred to here as Merck/Schering-Plough Pharmaceutical Company, LLC, (“MSP”) to develop and market new prescription medicines in the area of cholesterol management. This partnership, which functions as a separate entity from its parent organizations, currently markets Zetia® and Vytorin® in the United States. MSP has always been governed by policies and procedures that are in accordance with the laws and regulations that govern pharmaceutical marketing and selling activities in the United States. In addition, its policies and procedures are consistent with the recommendations set forth in “Compliance Program Guidance for Pharmaceutical Manufacturers,” published by the Office of Inspector General, U.S. Department of Health and Human Services (the “HHS-OIG Guidance”) and the provisions of the Code on Interactions with Healthcare Professionals created by the Pharmaceutical Research and Manufacturers of America (PhRMA Code). The goal of MSP’s Compliance Program has always been to maintain a culture that promotes the prevention, detection and resolution of potential violations of law or Company policy.

The fundamental elements of MSP’s Compliance Program as it relates to sales and marketing activities conducted by MSP sales representatives in the United States are described below. Moreover, MSP’s Compliance Program is dynamic, involving regular assessment and adjustment to ensure the Program is responsive to the Company’s evolving business and associated compliance risks.

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

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

MSP has the appropriate resources in place to support its commitment to Compliance. MSP has a Compliance Officer dedicated to support MSP’s culture of compliance. In addition, the executive committee reporting to the General Manager and Vice President of MSP generally provides oversight for the processes, training and implementation of policies needed to ensure full compliance with laws, regulations and policies that direct interactions with physicians and other customers in the United States.

## 2. Written Standards.

The development and distribution of written standards of conduct, as well as written policies, procedures and guidelines is a key element of MSP's Compliance Program.

- MSP has policies, procedures and guidelines that outline the specific behaviors required for day-to-day operations and outline how MSP employees are expected to conduct their activities. Among other things, these policies, procedures and guidelines address potential risk areas such as those identified in the HHS-OIG Guidance. For example, MSP has policies regulating: prescription drug sampling; MSP-led promotional and educational programs; financial support of independent continuing medical education; scientific research grants; consulting arrangements with healthcare professionals; service agreements with customers; and the provision of grants in support of healthcare-related initiatives sponsored by professional societies, patient advocacy groups, trade associations, charitable entities and other organizations.
- MSP's policy relating to professional representative interactions with healthcare professionals provides that such interactions must focus on: (1) providing current, accurate, and balanced information about MSP products, (2) transmitting sound scientific and educational information, and (3) supporting medical research and education. As a matter of policy, MSP employees are prohibited from offering healthcare professionals items of personal benefit, such as tickets to sporting events, support for office social events, gift certificates to stores, golf outings or athletic equipment.
- Under MSP policies, MSP personnel occasionally may provide healthcare professionals with approved educational or practice-related items that are not of substantial value. These materials are intended primarily to benefit patients and may include items such as medical textbooks, medical journals, or anatomical models. Items of minimal value may also be provided if they primarily are associated with a healthcare professional's practice. For example, items such as pens, notepads and similar "reminder items" with company logos may be distributed in modest quantities. Policy measures are designed to ensure that these items are provided in accordance with the PhRMA Code and the HHS-OIG Guidance.
- MSP policy also permits informational presentations and discussions by MSP representatives or others speaking on MSP's behalf. These events provide high quality clinical, disease and drug therapy information, are in accordance with FDA regulations, and are specifically designed to provide the type of information practicing medical and health care professionals have indicated to MSP that they need and find most useful in the treatment

of their patients. In connection with such presentations or discussions, meals may be offered to medical or health professionals provided the meals occur in a venue and manner conducive to informational communication. Policy measures are designed to ensure that these meals are provided in accordance with the PhRMA Code and the HHS-OIG Guidance.

- As required by California Health & Safety Code §§ 119400-119402, MSP has established an annual dollar limit on educational or practice-related items, items of minimal value and meals which MSP employees are permitted to provide to medical or health professionals in California under MSP policy. As of January 1, 2007, the annual limit of \$500 applies prospectively to educational or practice-related items, items of minimal value, and meals associated with informational presentations or discussions provided to medical or health professionals in California; and incorporates the limitations and definitions contained in the statute.
  - MSP's annual dollar limit does not include 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 educational scholarships and fair market value payments for legitimate professional services provided by healthcare or medical professionals. In addition, the annual dollar limit does not include reprints, printed advertising or promotional materials, and items provided for distribution to patients (e.g., patient-oriented health and disease management information).
  - MSP representatives call on fewer than 5% of the individuals licensed to prescribe pharmaceuticals in the State of California.

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

Another critical element of our Compliance Program is the education and training of our employees on their legal and ethical obligations under MSP policy and the laws, regulations and guidelines that govern pharmaceutical marketing and selling activities in the United States.

- MSP is committed to taking all necessary steps to effectively communicate our standards and procedures to all affected personnel. MSP's policies, procedures and guidelines are available to employees at all times through their computer systems.

- All MSP sales and marketing employees are required to participate in training as a condition of their employment. In addition, these employees will undergo periodic re-training and remedial training programs as necessary.
- The following training plan applies to all field-based employees. New hires receive testing and certification on MSP's Field Policy Letters and general sales and product training. This includes training to ensure compliance with federal laws and regulations that relate to pharmaceutical sales and marketing such as the Anti-Kickback Statute, the Prescription Drug Marketing Act, and FDA drug promotion regulations. After this initial training, there is periodic training aimed at recertifying field-based employees on relevant policies. Field-based employees in geographies with state or other region-specific legal or regulatory requirements also receive training specific to the local requirements.
- The following training plan applies to all other MSP employees. All other MSP employees engaged in sales and marketing activities receive periodic training. The training is designed to ensure compliance with federal laws such as: the Anti-Kickback Statute, the antitrust laws, and FDA drug promotion regulations. In addition, more specific training and testing is provided as needed to address the employee's roles and responsibilities within MSP.
- The content for all training is evaluated and updated periodically to ensure it remains relevant and current.

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

MSP strives to provide a work environment that encourages employees to communicate openly with management about all types of workplace issues. Accordingly, as a matter of policy, employees are encouraged to bring workplace issues of any type to the attention of management without fear of retaliation or recrimination. To support this concept, MSP has established the following resources:

- MSP encourages employees, as a first step, to seek out an immediate supervisor or manager to discuss workplace issues. If the matter is not successfully resolved, an employee may pursue the issue with his/her next level of management or Human Resources.
- MSP employees have access to an Ombudsman Program, managed by the Merck Corporate Compliance and Ethics Officer. This program complements MSP's primary resolution mechanisms described above by providing an alternative channel for employees to address work-related concerns, including conduct inconsistent with MSP's policies, practices, values and standards. The Program is available to all MSP employees and is designed to provide a "safe haven" where concerns can be addressed in confidence and without fear of reprisal. All conversations with the

Ombudsmen are kept confidential unless they raise issues of potential harm to an individual or MSP.

- MSP employees also have access to a confidential outside telephone line which MSP makes available to all MSP employees who wish to anonymously raise concerns about potential unethical or illegal behavior or violations of MSP policies. This telephone line is operated by an independent security firm who will forward reported concerns to the appropriate individuals for response or investigation. The telephone line is available 24 hours a day, 7 days a week.

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

MSP's Compliance Program includes monitoring, auditing, and ongoing evaluation regarding compliance with the company's policies and procedures. In accordance with the HHS-OIG Guidance, the nature of our reviews as well as the extent and frequency of our compliance monitoring and auditing varies according to a variety of factors, including new regulatory requirements, changes in business practices, and other considerations.

The primary responsibility for oversight is with line management. To assist managers with this responsibility, MSP provides them with reports from tracking and oversight systems that capture key compliance indicators to aid them in monitoring compliance with company policy and investigating any potential violations of policy. Management oversight is supplemented by audits.

MSP utilizes a combination of up-front planning, and periodic tracking and monitoring to comply with the annual dollar limit established pursuant to California Health & Safety Code §§ 119400-119402. At periodic sales planning meetings, representatives are allocated an amount of resources that they may use with a particular physician throughout the year. Adherence to the plan will then be monitored on an on-going basis.

## **6. Hiring.**

MSP is committed to hiring a workforce whose actions will reflect a high degree of integrity and ethics, recognizing that the ability to excel depends on the integrity, knowledge and skills of our people. Accordingly, MSP invests significant resources in identifying and hiring highly qualified and skilled individuals. In addition, prior to allowing the individual to commence employment with the Company, MSP performs a drug screening and background investigation of the individual. The background investigation includes verification of employment history, and education. MSP also performs a criminal background investigation that searches for any felony or misdemeanor on both a county and federal level. If deemed appropriate to the position, checks also will be conducted of professional certifications and licenses, motor vehicle records and credit history.

In many instances, employees of MSP come from one of its parent companies. In those instances, the employee will have gone through the pre-hiring screening process used by the parent company.

## **7. Responding to Potential Violations.**

A Compliance Program increases the likelihood of preventing, or at least identifying unlawful and unethical behavior. However, HHS-OIG recognizes that even an effective Compliance Program may not prevent all violations. As such, our Compliance Program requires the company to respond promptly to potential violations of law or company policy, and take appropriate disciplinary action. Specifically, MSP's Compliance Program includes a clearly defined violations process that sets out the potential consequences of violating the law or company policy. Although each situation is considered on a case-by-case basis, MSP policy requires that consistent and appropriate disciplinary action be taken to address inappropriate conduct and deter future violations. MSP also assesses whether identified violations are in part due to gaps in our policies, practices, or internal controls, and if so, takes appropriate action to prevent future violations.

MSP plans to continue its practice of ongoing refinements to its Compliance Program to take into account its business needs. MSP's Comprehensive Compliance Program will be updated to reflect such changes as necessary.

A copy of this document and/or MSP's written Declaration of the Company's adherence to the Comprehensive Compliance Program described above can be obtained by calling 1-866-637-2501.