

# Merck & Co., Inc. Comprehensive Compliance Program (U.S.)

## I. Introduction

Merck has a well-established Compliance Program that reflects Merck's longstanding commitment to compliance with the laws and regulations that govern pharmaceutical and vaccine marketing and selling activities in the United States. Merck's Compliance Program also is 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 Merck'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.

### Declaration of Compliance

To the best of its knowledge, information and belief, Merck & Co., Inc. was in compliance, in all material respects, with its Comprehensive Compliance Program and its good faith understanding of the requirements of California health and Safety Code §§ 119400-119402 during the period between January 1, 2015 to December 31, 2015.

A copy of this document can be obtained by calling 1-800-672-6372.

The fundamental elements of Merck's Compliance Program as it relates to sales and marketing activities in the United States are described below. Merck'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.

### Merck's Ethical Operating Standards Handbook:

Business Practices for U.S. Related Activities

[EOS Handbook](#)

[Download Code of Conduct Code of Conduct](#)

## II. Overview of Compliance Program

### 1. Leadership and Structure

Merck has the appropriate resources in place to support our commitment to compliance.

- The Merck pharmaceutical and vaccine divisions that engage in sales and marketing activities in the United States have a Compliance Officer dedicated to support Merck's culture of compliance within each division. The US Compliance Officer (Compliance Officer) has responsibility for corporate wide activities in the United States and for those activities that US Healthcare Providers conduct on Merck's behalf outside of the US. The Compliance Officer for the U.S. pharmaceutical operating division reports to the President of Global Pharmaceuticals and periodically to the Company's Board of Directors.
- The Compliance Officer manages a department of Compliance Professionals who provide guidance and oversight for the processes, training, and implementation needed to ensure full compliance with the laws, regulations and policies that direct interactions with physicians and other customers in the U.S. marketing and sales units.
- Merck is committed to ensuring that its Compliance Officer has the ability to effectuate change within the organization as necessary and to exercise independent judgment. The compliance function has unrestricted access to information, executives and meetings related to business operations.

### 2. Written Standards

The development and distribution of written standards of conduct, as well as written policies, procedures and guidelines has long been a key element of Merck's Compliance Program.

- Merck's Ethical Operating Standards (EOS) and the Merck Code of Conduct are our universal statement of the values, standards and ethical principles that guide our daily operations. The EOS and Code of Conduct are available to all employees on the Company's intranet and applies to everyone conducting business on behalf of Merck.
- In addition to its EOS and Code of Conduct, Merck has corporate policies, procedures and guidelines that outline the specific behaviors required for day-to-day operations and outline how Merck 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, Merck has policies regulating: prescription drug sampling; Merck-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.
- Merck's policy relating to Field Based Employees (FBE) interactions with healthcare professionals provides that such interactions must focus on: (1) providing current, accurate, and balanced information about Merck products, (2) transmitting sound scientific and educational information, and (3) supporting medical research and education. As a matter of policy, Merck Field Based Employees and Headquarter 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 or golf outings.
- Under Merck policies, Merck Field Based Employees 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 not 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 not be distributed. Merck Policies have been developed to be consistent with the PhRMA Code and the HHS-OIG Guidance.
- Merck policy also permits informational presentations and discussions by Merck Field Based Employees or others speaking on Merck'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 healthcare professionals have indicated to Merck that they need and find most useful in the treatment of their patients. In connection with such presentations or discussions, occasional modest meals may be offered to medical or healthcare 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, Merck has established an annual dollar limit on educational or practice-related items, items of minimal value and meals which Merck Field Based Employees are permitted to provide to medical or health professionals in California under Merck policy. As of July 1, 2006, the annual limit of \$2,000 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.
- Consistent with California Law Merck'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).
- The annual limit is not intended to serve as a spending objective or goal by Merck for all healthcare professionals in California. Rather, it is intended to establish an annual upper limit for those healthcare professionals with whom Merck employees interact across multiple therapeutic areas.
- Effective January 1, 2007 the reporting year is defined as the calendar year of January 1st through December 31st.
- The average annual expenditure by Merck for those medical or health care professionals is well below the established annual dollar limit.

- Some of the medical and healthcare professionals Merck calls on have practices spanning multiple therapeutic categories in which Merck has medicines and vaccines. Merck's pharmaceutical and vaccine line currently includes over 50 products that are actively promoted by Merck Field Based Employees. Because of the breadth of topic areas that are relevant to these practitioners, a larger number of discussions and informational presentations occur between these individuals and Merck Field Based Employees. It is in recognition of these instances that Merck's annual upper limit on expenditures for medical and healthcare professionals is currently set at \$2,000. (Collectively, these practitioners are referenced in the remainder of this document as the "Multi-Therapeutic Category Practitioners.") The largest component of these expenditures is modest meals associated with informational presentations and discussions. However, these expenditures also include the fair market value of educational and practice-related items provided to medical and health care professionals as set forth above.

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

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

- Merck is committed to taking all necessary steps to effectively communicate our standards and procedures to all affected Field Based and Headquarter personnel. Merck's Code of Conduct, corporate policies, procedures and guidelines are available to employees at all times through the Merck intranet.
- All Merck Field Based and Marketing Headquarter employees are required to participate in annual training as a condition of their employment. In addition, these employees will undergo periodic re-training and remedial training programs as necessary. The training process is overseen by distinct training departments.
- The following training plan applies to all Field Based Employees. New hires receive testing and certification on Merck's Field Policy Letters, Merck's Ethical Operating Standards 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 U.S. Headquarters employees ("HQ employees") engaged in marketing and sales activities. These employees receive annual training designed to ensure compliance with Merck's Policy Letters and Ethical Operating Standards and 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 HQ employees consistent with their roles and responsibilities within the company.
- The content for all training is evaluated and updated annually to ensure it remains relevant and current.

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

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

- Merck 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 is encouraged to pursue the issue with his/her next level of management or Human Resources.
- The Merck Ombudsman Program, managed by the Chief Ethics and Compliance Officer, complements Merck's primary resolution mechanisms described above by providing an alternative channel for employees to address work-related concerns, including conduct inconsistent with Merck's policies, practices, values and standards. The Program is available to all 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 Ombudsman are kept confidential unless they raise issues of potential harm to an individual or the Company. The Ombudsman is a neutral party who will listen to and review concerns as

an advocate for the Company's values and standards. The Ombudsman has a stand-alone office that is part of the Office of Ethics and independent of any Merck division.

- Merck also has a confidential outside telephone line made available to all employees who wish to anonymously raise concerns about potential unethical or illegal behavior or violations of Merck policies. This telephone line is operated by an independent firm who will forward reported concerns to the Merck Office of Ethics for response or investigation. The telephone line is available 24 hours a day, 7 days a week.
- The Office of Ethics is accountable for ensuring appropriate review and follow-up with respect to issues raised to the Ombudsman or via the confidential telephone line.

## **5. Auditing and Monitoring**

Merck'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. Results of auditing, monitoring and evaluation are, as appropriate, followed up on specifically, incorporated in training and communications strategies and considered when making choices in connection with ongoing general management of the business.

The primary responsibility for oversight is with line management. To assist managers with this responsibility, Merck 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.

Merck utilizes a combination of up-front planning, and monthly tracking and monitoring to comply with the annual dollar limit established pursuant to California Health & Safety Code §§ 119400-119402. At periodic sales planning meetings, Field Based Employees are allocated an amount of resources that they may use with physicians identified as Multi-Therapeutic Category Practitioners, as described in Section 2 above, throughout the year. Adherence to the plan will then be monitored on an on-going basis.

## **6. Hiring**

Merck 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, the Company 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, Merck performs a drug screening and background investigation of the individual. The background investigation includes verification of employment history, and education. Merck also performs a criminal background investigation that searches for any felony or misdemeanor on both a county and federal level and reviews all candidates against the Federal exclusions list. If deemed appropriate to the position, checks also will be conducted of professional certifications and licenses, motor vehicle records and credit history.

## **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 employees to report and the company to respond promptly to potential violations of law or company policy, and take appropriate disciplinary action. Specifically, Merck'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, Merck policy requires that consistent and appropriate disciplinary action be taken to address inappropriate conduct and deter future violations. Merck 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.

## **8. Conclusion**

In summation, a copy of this document and/or Merck's written Declaration of the Company's adherence to the Comprehensive Compliance Program described above can be obtained by calling 1-800-672-6372