Public

United States (U.S.) Comprehensive Compliance Program

Declaration of Compliance: To the best of its knowledge, information and belief, Merck Sharp & Dohme LLC., 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, 2025, to December 31, 2025.

Introduction

Our Company has a well-established Compliance Program that reflects our longstanding commitment to compliance with the laws and regulations that govern pharmaceutical and vaccine marketing and selling activities in the United States. Our Compliance Program is also 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 our 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 our Compliance Program as it relates to sales and marketing activities in the United States are described below. Our 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.

Overview of Compliance Program

1. Leadership and Structure

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

- Our business units that engage in sales and marketing activities in the United States have a Compliance Officer dedicated to support our Company's culture of compliance within each business unit. The US Compliance Officer (Compliance Officer) has responsibility for corporate wide activities conducted in the United States. The Compliance Officer for the U.S. pharmaceutical operating division reports to the Chief Ethics and Compliance Officer and periodically to the Audit Committee of the Company's Board of Directors.

- The US 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.

- Our Company is committed to ensuring that its US 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 our Company's Compliance Program.

- Our Company's Ethical Operating Standards (EOS) Handbook and 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 employees and contractors conducting business on behalf of our Company.

- In addition to its EOS and Code of Conduct, our Company has corporate policies, procedures, and guidelines that outline the specific behaviors required for day-to-day operations and outline how our 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, our Company has policies regulating prescription drug sampling; Company-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.

- Our policy relating to Field Based Employee (FBE) interactions with healthcare professionals provides that such interactions must focus on: (1) providing current, accurate, and balanced information about our products, (2) transmitting sound scientific and educational information, and (3) supporting medical research and education. As a matter of policy, Our FBE and Headquarter (HQ) 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 our policies, FBEs may occasionally provide healthcare professionals with approved educational items that advance disease or treatment education 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 are primarily 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. Our policies have been developed to be consistent with the PhRMA Code and the HHS-OIG Guidance.

- Our Company's policy also permits informational presentations and discussions by FBEs or others speaking on our 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 us 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, we have established an annual dollar limit on educational or practice-related items, items of minimal value, and meals which our FBEs are permitted to provide to medical or healthcare professionals in California under our 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 healthcare professionals in California; and incorporates the limitations and definitions contained in the statute.

- Consistent with California Law, our Company'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 our company for all healthcare professionals in California. Rather, it is intended to establish an annual upper limit for those healthcare professionals with whom our 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 us for those medical or healthcare professionals is well below the established annual dollar limit.

- Some of the medical and healthcare professionals our FBEs call on have practices spanning multiple therapeutic categories in which our company has medicines and vaccines. Our pharmaceutical and vaccine line currently includes numerous products that are actively promoted by our FBEs. 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 FBEs. For this reason, and consistent with California Law, our annual upper limit on expenditures for medical and healthcare professionals is currently set at $2,000. 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 healthcare professionals as set forth above.

3. Education and Training

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

- We are committed to taking all necessary steps to effectively communicate our standards and procedures to all affected FBEs and HQ personnel. Our Code of Conduct, corporate policies, procedures, and guidelines are always available to employees through our Company's intranet.

- All FBEs and HQ 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 FBEs. New hires receive testing and certification on our Field Policy Letters, our 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. FBEs 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. HQ employees engaged in marketing and sales activities. These employees receive annual training designed to ensure compliance with our Field 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 regularly to ensure it remains relevant and current.

4. Lines of Communication

We strive 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, we have established the following resources:

We encourage employees to raise concerns when they suspect activity that is unethical, illegal, or inconsistent with our Company policies. Employees have multiple channels through which they may raise concerns, including through their manager, human resources, legal, or the ethics and compliance office.

- Alternatively, employees can raise their concerns at msdethics.com, a confidential external channel that is accessible 24/7 in their preferred language, either online or by phone. When submitting a report via msdethics.com, employees have the option to remain anonymous, where permitted by law.

- The information provided through msdethics.com is relayed to an appropriate Company representative who is responsible for ensuring appropriate review and follow-up with respect to issues raised. Information provided is handled discreetly and shared only as needed to investigate and resolve an issue.

5. Auditing and Monitoring

Our 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, we provide 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.

We utilize 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.

6. Hiring

We are 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, we perform a drug screening and background investigation of the individual. The background investigation includes verification of employment history, and education. We also perform 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 lists. 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, our Compliance Program includes a clearly defined investigation 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, our policy requires that consistent and appropriate disciplinary action be taken to address inappropriate conduct and deter future violations. We also assess whether identified violations are in part due to gaps in our policies, practices, or internal controls, and if so, take appropriate action to prevent future violations.

8. Conclusion

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

Our Company's Business Practices for U.S. Related Activities

Download the Ethical Operating Standards Handbook

Download Code of Conduct