Eisai Inc. Comprehensive Compliance Program

Eisai’s ethics and compliance program is founded on Eisai’s human health care (hhc) mission: “We give our first thought to the patients and their families and contribute to increasing their benefits.” It is fundamental to our mission of being an hhc company that we comply with all laws that govern our businesses. It is an integral part of the hhc ideal that we achieve our corporate goals and implement our corporate mission on the basis of such compliance, and in accordance with the highest level of integrity, when our actions may affect the lives and health of many people. Eisai’s reputation – for integrity, honesty, fairness, candor and respect in all of its business dealings – is directly attributable to the highest ethical conduct of its directors, officers and employees.

Our Comprehensive Compliance Program (Compliance Program) is designed to meet the needs of our unique and dynamic business in the Americas region. Eisai’s Executive Team, including the company's chief ethics and compliance officer, oversee the company's compliance program, including compliance-related policies and procedures, education and training—all of which reflect the highest standards and are tailored to Merck's business and culture.

1. **Leadership and Structure**

Eisai has a Vice President and Chief Ethics and Compliance Officer (Compliance Officer) to oversee the administration of the Compliance Program in the Americas region. The Compliance Officer is responsible to develop, implement and monitor the Compliance Program.

The Compliance Officer is a member of the Executive Committee and regularly reports to that committee and the Global Compliance Committee regarding implementation of the Compliance Program. These committees provide input and oversight of compliance initiatives and ongoing programs on a regular basis. In addition to the oversight provided by these committees, the Compliance Officer reports regularly to the U.S. Board of Directors.

2. **Written Standards**

Eisai’s Compliance Handbook sets forth the legal and ethical standards and values that guide all Eisai colleagues worldwide in their daily activities. Additionally, the Company has adopted policies to address its legal and regulatory requirements, including a detailed “Interactions with Health Care Providers Policy” handbook to ensure that all interactions with Healthcare Providers focus on appropriate informational, scientific and educational exchanges. These policies conform to legal requirements, industry standards and the Office of Inspector General (OIG) Compliance Program Guidance for Pharmaceutical Manufacturers (OIG Guidance) and includes guidance relating to i) data integrity pertaining to government reimbursement practices; ii) kickbacks and other illegal remuneration; and iii) compliance with laws regulating drug samples.
Eisai has established annual spending limits of $2,000 as per California Business and Professional Code Section 119402(d)(1) for certain promotional activities directed toward health care professionals in California. This limit includes expenses related to meals, promotional materials or items or activities that Eisai may give or otherwise provide to a medical or health care professional. This limit does not include samples intended for patient use, bona fide business or consulting arrangements or independent educational or research grants. This limit is set as an upper limit, not a spending goal.

3. **Education and Training**

A key element of the Compliance Program is education and training so Eisai employees understand their legal and ethical obligations and specific requirements that impact their daily job responsibilities. Eisai has established a learning program for its employees that is directed towards informing them of the Company’s expectations for their behavior and the specific requirements of their jobs. We have a communication and training program to ensure that colleagues know where to go to access the policies and procedures impacting their jobs and that they receive updates on their training requirements.

4. **Internal Lines of Communication**

As part of Eisai’s Compliance Program, we have established means of ensuring that employees are kept up-to-date on important Company and compliance matters. Employees receive updates on policy changes and new compliance initiatives or training programs through internal communications, company intranet postings, or communications from senior management that are cascaded through the organization.

The Company’s toll-free anonymous disclosure program, known as our Compliance Helpline, facilitates communications regarding compliance with Company policies and procedures and federal and state laws and regulations. The Compliance Helpline is manned 24 hours a day, 7 days a week, and provides a means for employees to raise issues anonymously, and without fear of retribution or retaliation. This resource is available to any employee with compliance- or ethics-related questions or who wish to report in good faith a suspected violation. The Compliance Helpline can be accessed at 1-800-467-1391 or via the internet at [http://www.ethicspoint.com](http://www.ethicspoint.com).

5. **Auditing and Monitoring**

Eisai has established an audit program that includes activities to monitor, audit and evaluate compliance with the Company’s policies and procedures. The nature of these activities as well as the extent and frequency of our audit and monitoring activities is dependent upon many factors, including changing regulatory requirements, changes in business practices, and other considerations. The audit program is reviewed annually to ensure that it is focused on the significant business activities and risks and the audit plan is augmented regularly as a result of regular risk assessment activities.
6. **Responding to Potential Violations**

The Company has implemented policies that set out the consequences of violating law, regulations, or company policies and reporting instances of non-compliance to state and federal authorities, where required or appropriate. Although each situation is unique and considered on a case-by-case basis, we undertake appropriate disciplinary actions to address inappropriate conduct and deter future violations.

7. **Corrective Actions**

The Company is committed to preventing and detecting violations of laws and policies and takes appropriate corrective actions when necessary. The Company responds promptly to potential violations of law, regulations or company policies and takes appropriate disciplinary and corrective actions as necessary.