

# Compliance Handbook

**Eisai Network Companies**

Compliance Handbook 8th edition



American English Version

March 2021

## **Corporate Objective**

A human health care company capable of making a meaningful contribution under any healthcare system while observing the highest legal and ethical standards in its business activities.

## Message from the Chief Executive Officer

Corporate compliance incidents, also known as white-collar crimes, can have grave consequences for individuals and companies. On the one hand, in cases involving criminal intent, such as embezzlement of funds, the company would be required to claim compensation from the wrongdoer or pursue criminal proceedings. In all cases, the wrongdoer will have to leave the company. On the other hand, there are cases where a compliance violation is committed because the wrongdoer believes it is in the company's interest. One such example is cartels, whereby price fixing or production adjustments may falsely appear to improve profits temporarily. However, such incidents would lead to vast amount of fines that are overwhelmingly greater than any financial gains. Wrongdoers, both employees and directors, may face prison sentences. And it takes huge amounts of time and energy to resolve the problems created by the misconduct. It is wrong that such action might help the company. Compliance violations are never worth it.

Further, workplace cases such as harassment and discrimination cause enormous pain to those affected and significantly disrupt the organization and culture of the company.

Any manipulation or misrepresentation of data, information, or product quality poses a severe risk to the company. Such a transgression can shake the very foundations of a company, resulting in a loss of trust or the discontinuation of the company's business. It can even trigger the company's downfall or an unwanted merger.

You might get the sense that you can do something because no one else would find out; you might think it is okay because you see people around you doing the same; or you might feel it is permissible to some extent because it is within your discretion. But these kinds of thoughts are signs of something rotten in the person and the organization. There is no room whatsoever for such behavior in Eisai or for claims of extenuating circumstances.

I want to emphasize strongly to you all that compliance is not optional for Eisai. It is an absolute prerequisite for the trust placed in us by our valued patients and by all our stakeholders.

March 2021

**Haruo Naito**

Representative Corporate Officer and CEO



**Message from  
the Chair Person  
of Compliance  
Committee**

The lifestyles and business styles of people around the world have changed dramatically. In particular, the number of face-to-face opportunities between people has decreased significantly, making it

difficult to communicate in both life and business. We must respond quickly to changes without being bound by conventional methods.

In this way, as business practices change, compliance remains the same. I have been advising on Eisai's compliance promotion for over 20 years since the establishment of the Compliance Committee in Eisai. Today, Eisai has a great compliance program and promotion structure in place. However, this is meaningless if each person is not conscious and compliant.

Eisai has created a globally common compliance handbook. This Handbook is a collection of important things that each and every one of you must protect, regardless of country or region. In addition, the content presented in this handbook is based on more than 20 years of Eisai's compliance history, and its essence will not change even after repeated revisions.

March 2021

**D. Stuart Meiklejohn**

Chair Person of Compliance Committee



**Message from the  
Chief Compliance  
Officer**

In 2000, I was involved in launching the first global compliance program in Eisai as one of the staff members. At that time, the environment surrounding compliance varied from region to region, and I remember that there was much resistance in applying global compliance standards. However, thanks to the leadership of Mr. Meiklejohn of the Compliance Committee and other members, we were able to set a global compliance standard with a strong will. This has shaped the current compliance program of Eisai, and I am very proud to maintain it to this day.

As the times change, I feel that the demands for compliance have become more diverse, and also feel that the threshold for demands is constantly increasing. In revising this Handbook, I firmly accepted the changes and continued to think about what I should do to make Eisai better.

As you know, compliance-based business activities cannot be achieved only by the efforts of the Chief Compliance Officer and the Compliance Department. The most important thing is the constant effort of everyone reading this handbook. Please use this handbook to ensure that everything you do at Eisai “in compliance with all relevant laws and ethical standards.”

The most important thing to solve a compliance issue is to detect and respond in early stages. Eisai has a whistleblowing system in place to protect whistleblowers, so if you detect a compliance violation or something that might lead to it, please contact the Compliance Department promptly.

March 2021  
**Mitsuaki Tanaka**  
Chief Compliance Officer

*Mitsuaki Tanaka*



# Eisai Charter of Business Conduct

Established: March 2000

Revised: March 2021

We give first thoughts to patients and their families. We strive to increase the benefits that healthcare provides them and we conduct our business to meet their diversified healthcare needs worldwide. As a human health care (“*hhc*”) company, we develop and provide products and services that contribute to the well-being of patients and customers under any healthcare system.

In order to realize our corporate philosophy, we develop business activities that contribute to sustainable economic growth and the resolution of social issues, as well as make decisions and act appropriately and in a timely manner, in compliance with all relevant laws and ethical standards.

We hereby establish our Charter of Business Conduct as a statement of our commitment to compliance. Compliance is essential to the company’s existence and is given top priority in all corporate activities. Corporate executives recognize that it is their role to lead the employees by implementing the content and spirit of this Charter in all the work they do and in supervising those who work with them. By adhering to this Charter, they will inspire and encourage everyone to apply these standards in all their activities.

Everyone is expected to abide by the content and spirit of this Charter.

- 1.** We promote mutual respect and trust in our business relationships with our stakeholders including patients, customers, shareholders, investors, employees, healthcare providers, business partners and communities.
- 2.** We compete fairly, and do not tolerate bribery or any other form of corrupt business behavior.
- 3.** We appropriately manage information and ensure our records are accurate, complete, fair and secure.
- 4.** We appropriately disclose corporate information in a timely manner, and communicate with stakeholders transparently.
- 5.** We act in the workplace in accordance with the principles of fairness, respect, and non-discrimination with respect for diversity.
- 6.** We provide a work environment that takes health and safety into consideration.
- 7.** We comply with all relevant laws and regulations of each jurisdiction in which we do business and we conduct ourselves with the highest sense of ethics.
- 8.** We respect human rights and do not tolerate, within the scope of our business and in our supply chain, modern slavery such as child labor, forced labor and human trafficking.
- 9.** As a “good corporate citizen,” we contribute to the resolution of social issues and the development of society.
- 10.** We maintain fair and transparent relations with political and government entities.
- 11.** We shall not enter into, or to the extent we become aware we shall sever, relations with organized crime groups.
- 12.** We place global environmental protection as an important component of business operations and strive to maintain the environment.

# Compliance at Eisai

## 1 What does Compliance mean at Eisai?

Compliance at Eisai means not only abiding by written standards such as laws, regulations, and Eisai policies and procedures, but also upholding ethical standards that are integral to how we operate.

Eisai's ethical standards are, in all business activities, to give first thought to patients and their families, and to increase the benefit that healthcare provides them, as well as to behave with integrity, respect, and openness.

### INTEGRITY

We act with INTEGRITY, interact in a responsible manner, and aim to ensure that our communications with stakeholders are accurate, legitimate, and balanced.

### RESPECT

We interact with all our stakeholders with RESPECT. We commit to approach our stakeholders in an open manner.

### OPENNESS

We are committed to ensuring that OPENNESS is respected. We are open about our activities and interactions to stakeholders.

### Eisai Compliance

Laws and regulations,  
Eisai policies and procedures

Ethical standards  
Integrity, respect, openness

## 2 The Structure of the Compliance function at Eisai

The Chief Compliance Officer is responsible for developing a global compliance structure and for promoting the highest standards of compliance with laws and regulations, Eisai policies and procedures, and ethical standards of INTEGRITY, RESPECT, OPENNESS. In addition, Regional Compliance Officers and/or Regional Compliance Departments, are responsible for implementing global compliance initiatives as well as devising a Compliance Program and implementing Compliance activities specific to their regions.

Compliance activities periodically undergo objective reviews by Compliance Committee members who are external experts, such as lawyers from inside and outside Japan.

In Eisai, the Compliance Program includes having a compliance structure, Eisai policies and procedures, good communication and effective training, reporting and internal controls, and processes to enable employees to report compliance concerns.

### The Structure of the Compliance function in Eisai



## 3 The Regional Compliance function

The Compliance function, however it is structured in the various Regions in Eisai, is responsible for the implementation of the global and regional Compliance Program.

The Compliance function acts as a valued adviser to the business to achieve their objectives whether by way of consultation, guidance, or when someone raises a concern about non-compliance.

The Compliance function, in most cases, is also charged with carrying out investigations into allegations of potential non-compliance.

The aims of the Compliance function are to support individuals working for or on behalf of Eisai to meet the highest levels of compliance with laws and regulations, Eisai policies and procedures, and ethical standards.

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## Code of Conduct

### **A: What is Eisai's Code of Conduct?**

Eisai's Code of Conduct defines the ethical standards for all corporate executives and employees in accordance with the Eisai Charter of Business Conduct.

### **B: Who is this Code of Conduct for?**

This Code of Conduct applies to all corporate executives and employees.



The following pages outline the Code of Conduct,  
and provide specific examples of how the  
guidelines should be applied.

**CHECK!**

Code of Conduct

# Part

# 1



## What Eisai's Code of Conduct means to each of us

- 1.1 Our responsibilities
- 1.2 Additional responsibilities of corporate executives and managers
- 1.3 Asking questions and reporting compliance concerns



## 1.1 Our responsibilities

Corporate executives and employees are responsible for being trained on, understanding, and applying relevant laws and regulations, Eisai's ethical standards, policies and procedures, and rules that apply to our work.

Although it is difficult to be prepared for every possible situation in our daily work, this Handbook can help us recognize some potential issues and give us basic guidance on how to respond in different situations.

We should ask our superiors if we have questions or are unsure about how to deal with situations which would be difficult to judge only by the Handbook, policies, or procedures, or we are unsure how to apply Eisai's ethical standards in a given situation.

Eisai resources, such as the local or regional Compliance Contact or Helpdesk, Compliance Department ("Compliance"), Human Resources Department, or Legal Department, can also help if your superiors are unable to provide clear guidance, or if you are more comfortable discussing a concern with someone other than your superiors.

We have an obligation to report concerns regarding non-compliance with written standards and Eisai's ethical standards.

We are also obliged to cooperate with investigations conducted by the compliance function.

## 1.2

### Additional responsibilities of corporate executives and managers

In addition to the responsibilities described in “Our responsibilities” in the previous section, corporate executives and managers are not only expected to lead by example, but also must guide and train employees when applying relevant laws and regulations, Eisai's ethical standards, policies and procedures to our day-to-day activities.

Corporate executives and managers are responsible for ensuring that compliance concerns in their area are properly handled and resolved. Prompt and accurate internal reporting of compliance concerns is essential to the success of the compliance program. The compliance performance of corporate executives and managers is a critical part of their management performance and they are evaluated on that basis.

Eisai gives its corporate executives and managers responsibilities for the compliance program, but the Board of Directors oversee the overall implementation of the compliance program and is responsible for ensuring that appropriate structures and systems to enforce compliance are in place and are operated effectively.



## 1.3

### Asking questions and reporting compliance concerns

It is everyone's responsibility to ensure that laws and regulations, and Eisai's policies, procedures, and ethical standards are upheld. When the right thing to do is not clear to us or something does not seem right, we should ask questions or report our concerns. Failing to do the right thing may also damage Eisai's business, reputation, and patients.

If we are unsure that what we or our colleagues are doing complies with written and ethical standards, or when we become aware of non-compliance, we should speak with our superiors or consult with Compliance, Human Resources, Legal, or the Relevant Department as appropriate. The earlier the company knows about them, the sooner it can investigate and take appropriate action.

#### 1.3.1 Reporting compliance concerns

We should always report something we believe does not comply with relevant laws and regulations, and Eisai's policies, procedures, and ethical standards. If we are not sure, we should contact Compliance.

#### Compliance can help:

- when we are not sure that what we or our colleagues are doing is compliant or ethical;
- if we want to speak to someone other than our superiors, or we do not believe that our superiors' advice meets Eisai's standards; and
- when we report an activity that may not comply with policies, procedures, and ethical standards.

**Compliance cannot help:**

- with advice for personal legal issues or other issues not related to work at Eisai; or
- if we knowingly make a false compliance report.

**1.3.2  
Policy of  
non-retaliation**

Eisai encourages everyone to report compliance concerns and does not tolerate attempts to stop someone from making a report. No one will be punished or disciplined for making a report in good faith. Additionally we will not allow anyone to interfere with an investigation of a compliance concern or retaliate against the person who reported it. Any attempt to interfere with an investigation or to retaliate may result in disciplinary action.

The policy of non-retaliation applies to every Eisai employee, including the report investigator and individuals cooperating with the investigation.



**1.3.3**  
**Confidentiality**

Be assured that reports of compliance concerns will be treated confidentially and information will be shared only in order to carry out any necessary investigation.

Corporate executives and employees who have been asked by Compliance to investigate are prohibited from disclosing information regarding the matter to others unless authorized by Compliance.

**Scenario & Advice**



I think a colleague may have violated Eisai policy. What should I do?



You should report it to your superiors or Compliance.

Code of Conduct

# Part

# 2



## Our working environment

- 2.1 Discrimination**
- 2.2 Harassment**
- 2.3 Health and safety**
- 2.4 Abuse of drugs and alcohol**



## 2.1

### Discrimination

Eisai respects the human rights of everyone who works for Eisai. Eisai welcomes and respects diversities, and believes in the fair treatment of everyone. Eisai policies are intended to encourage the professional growth and development of everyone in a work environment that is free from discrimination.

All of our activities, including recruitment, training, exchange, annual evaluations and promotions, reflect those policies.

Eisai does not tolerate any discrimination in our organization.

**Examples of discrimination include, but are not limited to:**

**race, physical characteristics such as color, age, pregnancy, gender, sexual orientation, ethnicity, disability, religion, political affiliation, union membership, or marital status, etc.**

**We should**

- treat everyone with respect.

**We should not**

- make decisions regarding any employee or applicant based on attributes not related to the person's job performance, behavior, or qualifications.

## 2.2

### Harassment

Eisai does not tolerate anyone making sexual advances toward any corporate executives and employees in the workplace or work-related environment, or taking intimidating or offensive actions that create a hostile working environment.

Everyone has the right to work in a place that is free from harassment and no one should engage in conduct that constitutes harassment.

#### We should

- treat everyone with respect and act as professionals.

#### We should not

- make or use sexual or other offensive or inappropriate comments, pictures, or written text.



**Scenario & Advice**



A colleague talks about sexual matters and tells sexual jokes during lunch break. What should I do?



Behaviors or actions which make you uncomfortable and unreasonably interfere with your work performance may be considered harassment. To some extent, this is a question of degree, but in appropriate cases, you should let your colleague know that this behavior is offensive to you or your colleagues and ask him or her to stop. You may also consult with your superiors, Compliance, or Human Resources for further guidance.

**Scenario & Advice**



A colleague of mine always yells at me. What should I do?



Such behavior by your colleague may be considered harassment. Please consult with your superiors, Compliance or Human Resources.

## 2.3

### Health and safety

Eisai provides a work environment that complies with health and safety laws and regulations. We should all be aware of the safety procedures applicable to our activities and follow them. We must immediately report any accident, or unsafe or potentially hazardous practice or condition, including actual or potential security risks, to our superiors or the relevant department.

Eisai believes that ensuring the safety of employees, who play a key role in realizing *hhc*, is always a top priority. In the event of a pandemic, disaster, etc., we must endeavor to ensure the health and safety of ourselves and our families in accordance with the rules of procedures of administrative instructions regarding crisis management established by each country or region.

Certain areas of our business, such as Research and Development and manufacturing, involve the handling of materials and equipment that can pose hazards to the health and safety of employees, and may impact the environment, which are regulated by laws.

If we are involved in these types of activity, we should adhere to the relevant laws and regulations, Eisai policies, procedures, and rules regarding how to work with these materials or equipment.

#### We should

- be aware that not complying with health and safety laws, regulations, Eisai policies and procedures can lead to serious health and safety problems;
- obtain written approval from the appropriate superiors if there are no relevant laws and regulations, or Eisai policies or procedures related to health and safety; and
- immediately report accidents and unsafe or potentially dangerous practices to superiors or the relevant departments.

## 2.4

### Abuse of drugs and alcohol

The abuse of drugs and alcohol not only can lead to significant health problems but anyone under the influence of drugs or alcohol while in the workplace, can be a hazard to themselves and the others. Eisai does not allow the use or unauthorized possession of illegal drugs at work. The consumption of alcohol on site without permission is also prohibited.

#### We should

- be aware that the abuse of drugs or alcohol can be dangerous in the workplace.

#### We should not

- drink alcohol in the workplace without appropriate permission.

#### Scenario & Advice



We want to hold a celebration for the launch of our new product in our department. We want to serve food and alcoholic beverages. Since it is a celebration, is it all right to have alcohol at work?



It might be, but in any event, you must obtain appropriate managerial approval or approval as set out in your local policy before you have alcohol at a work event.

Code of Conduct

# Part

# 3

## Business activities

- 3.1 Research and development**
- 3.2 Manufacturing and distribution**
- 3.3 Promotional communication**
- 3.4 Adverse events and safety**
- 3.5 Interactions with Healthcare providers, Healthcare organizations and Patient Groups, etc.**
- 3.6 Fair trade and competition practices**



## 3.1

### Research and development

Research and Development activities are the basis of Eisai's business and are essential to achieve our *hhc* mission. We engage in Research and Development activities that comply with all regulations and internationally recognized standards (e.g., Good Laboratory Practice (GLP) and Good Clinical Practice (GCP)), and we adhere to high ethical standards.

#### 3.1.1

##### Respect for clinical trial participants

Eisai respects the principles of GCP for clinical trials including the human rights, safety, and ethical considerations of trial participants. Prior to participating in a clinical trial, sufficient explanation must be given and written consent from the clinical trial participant must be obtained. Ensuring safety in clinical trials is a top priority. Special attention should be paid to First in Human (FIH) study, which is administered to humans for the first time.

#### 3.1.2

##### Data integrity

Data integrity, meaning the reliability and trustworthiness of data throughout its life cycle, is of the utmost importance to Eisai. We recognize that in order to build trust with the public and to support our scientific discoveries, we must ensure that the data supporting those discoveries are sound and secure. Eisai maintains policies and conducts training to ensure that we are adhering to principles that preserve data integrity, especially in our clinical trial work.

### 3.1.3 Disclosure of clinical results

We must disclose, in a timely and accurate fashion, clinical trial results, regardless of outcome.

### 3.1.4 Handling regulated chemicals and materials

In the process of Research and Development, we create and handle various chemicals and materials such as narcotics, anti-hypnotics (and their raw materials), psycho-pharmaceuticals, and other hazardous chemicals.

It is necessary to follow appropriate procedures to create and handle such chemicals and materials.

Chemicals and materials may be hazardous if they are not properly handled (including living organisms and radioactive materials) and may impact the environment (including genetically modified organisms). Eisai adheres to all relevant laws and regulations governing the appropriate handling of such substances.



### 3.1.5 Animal research

Eisai accepts that animal research is a necessary and required part of verifying safety and efficacy in the development of new drugs. We are dedicated to the humane care and treatment of the laboratory animals we use. Our animal research is overseen and guided by an Institutional Animal Care and Use Committee (IACUC), which includes external specialists.

Our research is conducted with scientific rigor, and due consideration is given to the well-being of the animals as well as to the 3R Principles of animal research:

- Replacement : Evaluating alternative techniques for animal research
- Reduction : Reducing the number of animals used to a minimum
- Refinement : Minimizing pain and suffering of animals to be used in research

#### **We should**

- prioritize patient safety prior to conducting testing on humans;
- conduct our Research and Development activities strictly in accordance with Eisai's policies and procedures;
- take steps to secure appropriate intellectual property protection for any Research and Development work Eisai does; and
- follow Eisai's guidelines on preserving data integrity and disclosing truthful and accurate results from clinical trial(s).

## 3.2

### Manufacturing and distribution

Eisai's manufacturing and distribution activities comply with all laws, regulations, and internationally recognized standards (e.g., Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP)). Eisai manufactures pharmaceutical products of high quality to ensure the health and safety of patients. We carry out our manufacturing activities with due regard for health, safety, and the environment. In addition, manufacturing and quality activities must be carried out in accordance with the methods or conditions for which the product has been approved by the authorities.

We have a mission and responsibility to maintain a stable supply of high-quality medicines. In order to achieve that goal, we must strive to ensure quality with a thorough system in all processes from manufacturing to distribution.

In order to ensure the quality of pharmaceutical products, we carry out appropriate raw material procurement, manufacturing control, and quality control, not only at our own factories but also at contract manufacturing companies, and it is necessary to build and implement a mechanism to ensure quality at the distribution stage.

We need to have a management system in place to prevent acts that violate GMP and GDP-related laws, Eisai policies and procedures.

#### We should

- ensure that there is a system for manufacturing and distributing high-quality pharmaceutical products; and
- be aware of and report any events and actions that raise doubts about the quality of pharmaceutical products to our superiors or the Quality Assurance Department.

#### We should not

- violate GMP, GDP, and other laws and regulations, or related Eisai policies and rules; or
- use manufacturing methods and quality control that differ from the conditions for approval by the regulatory authorities.

## 3.3

### Promotional communication

Eisai markets and promotes its pharmaceutical products worldwide. We provide accurate and balanced scientific information, and promote our products only for the uses for which they have been approved by the applicable regulatory authorities.

“Promotion” means any activity undertaken, organized, or sponsored by a pharmaceutical company which is directed at Healthcare Providers (HCPs) to promote the prescription, recommendation, supply, administration, or consumption of its pharmaceutical products through all methods of communication, including the Internet. When engaging in promotional activities with HCPs, we are expected to be familiar with local laws and regulations for such engagements in our home country. Promotion in a manner not consistent with the approved label is prohibited and promotion of drugs prior to approval is also prohibited. All promotional materials must be reviewed and approved in accordance with local processes and may be used only for the approved purpose.

#### We should

- provide accurate and balanced scientific information regarding our products’ appropriate use and safety information; and
- conduct promotional activities using only materials that have been approved by the relevant department in our company.

#### We should not

- conduct promotional activities inconsistent with the approved label or promote drugs prior to approval.

**Scenario & Advice**

I found an article in a reputable medical journal regarding one of our products. May I circulate it to our sales representatives to use as a reference?



Not unless it has been approved by the relevant department. Sales representatives may use only those documents and materials that the relevant department in our company has reviewed and approved for promotion and advertising.



## 3.4

### Adverse events and safety

The safety of our products, whether they are under development or on the market, is fundamental to our *hhc* mission. We are obliged by law to collect and report all information regarding the safety of our products.

Eisai is responsible for reporting adverse events to governmental or regulatory authorities. If any of us becomes aware of an adverse event related to an Eisai product, we should immediately report it to our local Pharmacovigilance Department in accordance with local standards.

If we are not sure how to proceed, we must ask our superiors or contact our local Pharmacovigilance Department.

#### We should

- report immediately all adverse events and safety information on marketed products, as well as on products being used in clinical trials, to the appropriate Local Safety Officer (LSO) or Pharmacovigilance Department.

#### We should not

- ignore or attempt to conceal adverse information about our products.

**Scenario & Advice**

A friend of my friend has posted on social media that they felt unwell after taking an Eisai product. Do I need to report it to someone?



Yes. You must report the message you have seen to your Local Safety Officer (LSO) or Pharmacovigilance Department in accordance with your local procedures.



## 3.5

### Interactions with Healthcare providers, Healthcare organizations and Patient Groups, etc.

We engage in various interactions with HCPs and Healthcare Organizations (HCOs) through promotional activities, including clinical research, sharing the best treatments, and exchanging information on how new drugs adapt to patients' illnesses, etc. Our mission, the desire to contribute to patient's well-being, is our corporate philosophy and the core of our business. In order to fulfil our *hhc* mission, Eisai spends time with patients or caregivers to understand their true needs, which ultimately helps to drive innovation.

In all of these and other interactions, it is important that we ensure that any interactions with patients or HCPs are in accordance with applicable laws, regulations, and Eisai policies and procedures.

#### **We should keep in mind the following when interacting with HCPs, HCOs, and Patient Groups:**

- **Interact with HCPs and HCOs only for legitimate business purposes.**
- **Follow the various local laws, regulations, policies, and procedures applicable to interactions with HCPs and HCOs or Patient Groups.**
- **Ensure that any compensation provided to HCPs, HCOs, or patients is in accordance with fair market value for the particular service provided.**

#### **Disclosure of payments to HCPs, HCOs and Patient Groups**

The collaboration Eisai has with HCPs, HCOs and Patient Groups is important to us. In many areas where Eisai does business, we are sought reporting on the interactions with HCPs, HCOs and Patient Groups as a pharmaceutical company. We need to comply with local or national disclosure rules, provide necessary information, and may need to disclose payments to HCPs, HCOs, and Patient Groups.

## 3.6

### Fair trade and competition practices

Eisai's policy is to compete fairly and legitimately, and to comply with anti-trust and competition laws in each country in which we operate. Acts or practices of unfair restraint of trade, for example, cartels, price-fixing, etc., are prohibited. In addition, any discussion of pricing or discounts must be done in accordance with local standards.

#### Dealings with competitors, distributors, customers, and suppliers

Certain formal or informal agreements or understandings with competitors, distributors, customers, and suppliers ("Third Parties") may be prohibited under competition laws. In some cases, even discussion about the sensitive topics listed below may violate those laws. Therefore, we need to seek guidance from our local Legal Department before having any interaction involving these sensitive topics (listed below).

#### Sensitive topics for discussion with Third Parties

- Pricing, costs, or profits
- Terms or conditions of sale (including credit extensions or information)
- Entering or leaving, or dividing with one or more other companies, products, services, or geographic markets
- Market share or production or sales volume
- Decisions to bid or quote or otherwise divide up customers, suppliers, or distribution channels
- Whether and how diligently to pursue R&D projects
- Terms under which a purchaser of our products resells the products (including price or whether the purchaser can resell)
- Unfair restriction of competitors, etc., manufacturing, purchase, sale, or provision of products or services to another party

<b>We should</b>	<ul style="list-style-type: none"><li>• take measures to avoid discussion of sensitive topics with Third Parties and, if required, remove ourselves from any such contact at the earliest opportunity;</li><li>• obtain prior written approval from Legal Department for any agreement or understanding with any Third Parties about any sensitive topic; and</li><li>• report contact with Third Parties in line with company policy.</li></ul>
<b>We should not</b>	<ul style="list-style-type: none"><li>• communicate or agree with Third Parties about sensitive topics without consulting with Legal Department.</li></ul>

**Scenario & Advice**



I just want to talk to other market participants about some issues having to do with standard practices, which I think will be in all our interests. Is there any reason I can't do that?



Yes, there may be. Competition laws assert that markets should not be without competition. Competitors are supposed to make independent business decisions. If they have agreements or understandings with their competitors about sensitive topics, they may violate competition laws in the process. Eisai will not tolerate such actions, which may expose the individuals involved, as well as Eisai, to legal liability.

Code of Conduct

# Part

# 4

## Fraud prevention

- 4.1 Fraud risk and prevention
- 4.2 Conflicts of interest
- 4.3 Corrupt practices and bribery
- 4.4 Misappropriation of assets
- 4.5 Proper financial reporting
- 4.6 Prevention of data fraud



## 4.1

### Fraud risk and prevention

Eisai provides guidelines to detect and prevent fraud, misappropriation, and other infringements. Fraud is defined as the intentional, false representation or concealment of a significant fact which brings great detriment. We should well understand the types of infringements that could occur within the scope of our work.

The following risks of fraud exist around us. We need to take measures to prevent fraud, such as by strengthening internal controls.

#### Examples of Fraud risks

- **Conflict of interest** (a situation in which one's interests or those of a business partner are prioritized over Eisai's interest in transactions with interested business partners)
- **Bribery** (providing money or goods to civil servants, etc.), illegal rewards, etc.
- **False expense reimbursement, expense inflating, private purchase, asset theft/unauthorized use, etc.**
- **Finance** (overstatement of sales/assets, concealment of liabilities, inappropriate asset valuation, etc.)
- **Non-financial** (falsification of in-house materials and/or certificates, data fraud, etc.)



We must comply with the laws, regulations, and Eisai policies and procedures related to our duties. Below are the various global guidelines Eisai has implemented to help prevent fraud.

#### **Guidelines for preventing fraud**

- Eisai Internal Control Policy
- Eisai Internal Control Guideline
- Eisai Global Code of Conduct for Business Partners
- Eisai Guideline for Segregation of Duties
- Eisai's Anti-Bribery and Anti-Corruption Policy

#### **Due diligence related to business partners**

Eisai may be liable for fraudulent activities by our business partners. We need to ensure that our business partners, in doing business for us, comply with the same standards we set for ourselves. We must properly perform due diligence on our business partners in accordance with the following global policies and local laws, policies, guidelines, and procedures before we start business with a new partner.

- Eisai Global Code of Conduct for Business Partners
- Eisai's Anti-Bribery and Anti-Corruption Policy
- Eisai Sustainable Procurement Policy
- Human Rights Policy

## 4.2

### Conflicts of interest

When we make professional judgments or act on behalf of Eisai, we are responsible for doing so impartially and in the best interests of the company. A conflict of interest exists when our personal interest is inconsistent with those of Eisai's and causes conflicting loyalties. This conflict may cause us to make a biased business decision that may not be in Eisai's best interests.

If there may be such possibilities existed actual conflicts occurred, we should report them to our superiors so that appropriate solutions can be found, such as removing ourselves from the decision-making process.

#### Examples of potential conflicts

- **Accepting a position with an existing or potential business partner or competitors while employed at Eisai**
- **Accepting anything of value including cash, gifts or entertainment, or favors from a business partner**
- **Owning shares of existing or potential business partner or competitors**
- **Conducting business with companies owned by family members or friends**

#### Scenario & Advice



I have some shares of a company that does business with Eisai. Do I have to disclose this information to Eisai?



There may be an issue with your owning shares of a company that does business with Eisai, and you must disclose this information to Eisai. Your ownership of the shares means you have a personal interest that may be different from Eisai's and the potential for a financial gain at Eisai's expense. You need to let Eisai determine how to deal with the situation.

## 4.3

### Corrupt practices and bribery

Eisai's policy prohibits bribery including facilitation payments\* or other corrupt conduct in Eisai business dealings, either directly or by third parties acting on our behalf.

Many countries have laws, regulations, rules, codes, and guidelines ("laws") that prohibit bribery of public officials or any other private persons or organizations. These laws forbid making, offering, or promising any payment or giving anything of value to public officials or any other private persons or organizations for the purpose of inappropriately influencing decisions by public officials, private persons, or organizations, to secure improper acts in connection with the supply of goods or services to or from Eisai. We should recognize that violation of these laws may result in criminal charges not only against Eisai but individuals as well.

Additionally, because our pharmaceutical business is regulated by many public authorities in and around the world, we must ensure that Eisai has appropriate interactions with such authorities and that communications with such authorities are accurate, complete, timely, and transparent.

\* Facilitation payments mean payments of a small amount of money for the purpose of facilitating procedures related to administrative services.



**We should**

- follow written standards for dealing with third parties, whether they are public officials or any other individuals or organizations;
- obtain approvals for all gifts, hospitalities, and expenses in accordance with local standards; and
- report to superiors, Compliance, or the Relevant Departments in case to witness or to recognize any suspicious transactions by a third party acting on behalf of Eisai.

**We should not**

- give, promise, or offer anything of value which is or may be perceived as an inducement for improper conduct; or
- contract with a third party without conducting appropriate due diligence.



## 4.4

### Misappropriation of assets

We need to properly manage the appropriate level of internal controls, separate responsibilities, establish approval authorities, and prevent the diversion of assets. Misappropriation of assets may include false settlement of expenses, inflated expenses, private purchases, theft or misuse of assets, etc. It is said that these frauds often allow employees to gain profits within their responsibilities without being known to others. We must properly protect assets and use and settle expenses.

#### 4.4.1

##### Asset preservation

We are responsible for preserving assets so that they are acquired, used, and disposed of under due process and approval. Unauthorized or inadvertent acquisition, use, or disposal of assets can result in significant damage to or impact on Eisai's property and social credibility, as well as financial loss. Eisai's assets include tangible assets such as land, buildings, machinery, equipment, inventory, computers, and cash; and intangible assets such as intellectual property (patents, trademarks, copyrights, etc.) and confidential information. We must properly preserve these assets.

#### 4.4.2

##### Use of expenses

Proper use and settlement of expenses is the basis of business activities. Eisai does not allow false settlement of expenses, inflated expenses, private purchases, or other unauthorized use of expenses. Corporate executives and employees must properly use and settle their expenses in accordance with the rules regarding the use and settlement of expenses.

## 4.5

### Proper financial reporting

As we are a publicly listed company, we are required to establish, develop, and implement internal controls and accurately disclose information about certain types of corporate activity in our annual reports. We do not tolerate fraudulent activities, such as overstatement of sales or assets, hiding of liabilities, or improper asset valuation.

In order for Eisai to fulfil its responsibility to disclose appropriate corporate information and to make appropriate business performance decisions, it is important to create and store transaction records fairly and appropriately. The same applies to transactions conducted not only with our own company's expenses but also to those conducted with expenditures from outside Eisai, such as subsidies.

We must clarify accounting facts and properly create transaction records in accordance with Eisai's rules so that the actual conditions of purchasing, inventory control, sales recording, etc., are properly reflected.

### Report of fraudulent accounting

We are obliged to report any false or counterfeit records of corporate books in the event that we detect that there are funds or assets that are not recorded in our accounting books. If we detect or suspect fraudulent accounting, we must contact Compliance immediately.



# 4.6

## Prevention of data fraud

We have the opportunity to acquire important data in all operations, including finance, Research & Development, clinical development, manufacturing, and quality assurance.

We must ensure the reliability of our data in accordance with policies, rules, and laws set by each country and region or by each department. Forgery or tampering with data is never tolerated, and data must be acquired, verified, stored and used in an appropriate manner. In addition, it is necessary to establish an appropriate mechanism to deal with fraudulent activities (fabrication of non-existent data and results, falsification of obtained data, concealment of inconvenient data and results, plagiarism of the results of the research of others, etc.).

In the event that we detect or suspect fraud, we must contact Compliance.

**We should**

- obtain, verify, store and use data related to finance, R&D, manufacturing, or quality in an appropriate manner, and establish an appropriate mechanism to prevent fraudulent activity; and
- immediately report to the superiors, Compliance, or the Relevant Department if we detect or suspect fraud, negligence, or improper operation related to data such as finance, R&D, manufacturing, or quality assurance.

**We should not**

- fabricate, falsify, conceal, or steal data or records such as finance, R&D, manufacturing, or quality assurance, etc.



Code of Conduct

# Part

# 5

## Proper use and management of information

- 5.1 Keeping records
- 5.2 Intellectual property
- 5.3 Appropriate management of information assets
- 5.4 Use of social media
- 5.5 Insider information and trading



## 5.1

### Keeping records

Documents are the records of a company. Individuals may remember events, but their memories are not consistently reliable. People inside and outside the company regard documentary records as much more important in trying to reconstruct things that happened in the past.

Not everything that happens needs to be documented. But we need to be aware that when we write emails or other messages, when we leave voice mails, and even when we have telephone conversations, if they are recorded, we are creating documents.

It is essential that documents be created for matters that need to be documented. There are many laws, rules, regulations, and Eisai policies and procedures that cover these topics. We need to be fully aware of the ones that apply to our work. It is also essential that when documents are created, they be timely, accurately and thoughtfully prepared so they are not misunderstood later or taken out of their proper context. Retained records must have a retention period that suits their purpose.

The knowing creation of false documentation, the improper alteration of documents and the intentional destruction of documents within approved retention period — all these things make it impossible to rely on the company's memory. Such misconduct is a violation of compliance and will be punished, up to and including termination from employment.



## 5.2

### Intellectual property

We spend a great deal of time, effort, and money on developing valuable new products to improve patients' health and quality of life. The course of this product development, may give rise to valuable assets in the form of intellectual property rights such as patent rights, design rights, trademark rights, copyrights, expertise, or trade secrets and these to be protected and secured. It is important to remember that any asset an employee creates while employed by Eisai is the property of Eisai but not the employee.

We must also respect intellectual property rights which belong to other people or companies, and we may not use intellectual property owned by a third party without the third party's permission.

#### Scenario & Advice



I found a third party's product with a name and packaging substantially similar to one of our products. Is there anything I can do?



Our product names and product packaging designs are protected under trademark laws or relative laws in most countries. Such protection given by laws may be seriously undermined if Eisai does not take appropriate countermeasures immediately. Therefore, if you find such a product, please contact Compliance as soon as possible so Eisai can take appropriate actions.

## 5.3

### Appropriate management of information assets

Eisai has established a management system in place for data protection and legal compliance. Also, Eisai manage IT security risks, including personal information and confidential information.

If personal or confidential information is leaked fraudulently or accidentally, it may cause not only financial losses but also serious damages to or impact on Eisai's property and social credibility. In the unlikely event that it is leaked, it is important to take prompt action to minimize the damage. If we suspect a leak, contact our superiors and Compliance.

#### 5.3.1 Protection of personal data

In the course of its business, Eisai obtains personal information about its employees, patients, healthcare providers, suppliers, customers and contractors. Personal information designated for protection is defined in accordance with local and national laws. Generally speaking, it may be any information that identifies living individuals. Examples include lists of employees, and records that show their birth date, government-issued identification number or other identifying information, or medical information. In particular, personal information that requires careful handling must be handled strictly. Eisai is committed to complying with data protection laws in and around the world. Improper use of personal information may cause irreparable damages to the rights and interests of the individuals, and may also result in the imposition of penalties on the company. In addition, the trust of others toward the company may be damaged. We are responsible for properly acquiring, using, managing and storing data.

**Keep the following in mind  
when handling personal information**

- At the time of acquisition, specify the purpose of use and obtain the consent of the person for that use if required.
- Do not use the information for any other purposes other than consented ones.
- Be aware of all local laws and regulations regarding personal data protection when handling, storing, transferring, or receiving personal data across the borders of countries and regions.
- When we identify the loss or leak of personal information, or become aware of the possibility, we must contact the superiors or the departments in charge of protection of personal information.

**5.3.2  
Confidential  
information**

Confidential information is an important Eisai asset. Confidential information includes anything from inventions, know-hows, and research results, financial data and customer lists etc. Confidential information is defined as “information used in the business of a company, such as technically or commercially useful information owned by the company, which is managed by the company as confidential.”

Disclosing confidential information intentionally or accidentally might undermine our business. Therefore, we must make every effort seriously and diligently to protect our confidential information.

Please note that if some information, despite being confidential information, is not managed appropriately, we may lose valuable legal protection that would otherwise apply to it.

Confidential information received from other people or companies is their property. When we come across information from them in our work or everyday life, we may be required to obtain the necessary permission from them to use it.

**5.3.3**  
**Information and**  
**technology security**

Eisai takes Information and Technology (“IT”) security seriously and has policies, procedures, and systems in place to help prevent unauthorized access, leakage, and disruption of information held in its IT systems.

On the other hand, the risk of cyber attacks such as targeted attack emails are increasing.

If a company device, laptop or computer is infected with a virus by a targeted attack email, the network system may go down, hinder Eisai’s business, or occur leakage of confidential or personal information, so we must use IT systems properly in accordance with Eisai policies and procedures.

<b>We should</b>	<ul style="list-style-type: none"> <li>• get the approval of the superiors and the manager responsible for Information Security in advance if we need to share confidential information with a third party; and</li> <li>• when sending emails, facsimiles, social media, and other messages, ensure they are sent only to the proper recipients.</li> </ul>
<b>We should not</b>	<ul style="list-style-type: none"> <li>• discuss confidential information in elevators, hallways, restaurants, airplanes, trains, or any other public places where unspecified people come and go;</li> <li>• bring in confidential information that belongs to another company that a new colleague may have previously worked for;</li> <li>• take confidential information when leaving Eisai or provide Eisai’s confidential information to any third party without prior and proper authorization; or</li> <li>• open attachments on emails that may contain computer viruses, or access URLs that may be infected with computer viruses.</li> </ul>

## 5.4

### Use of social media

We must understand the characteristics of social media, be aware of our responsibility as members of Eisai, and use social media with good sense even when using social media in private. In addition, it is necessary to recognize that it can impact the impression of Eisai depending on the content itself and how it is perceived by third parties.

The following are the principals for using social media in private. If such guidances of using social media are defined in each countries or regions, it is required to act in accordance with relevant guidelines.

1. Do not publish, post, or release any information owned by Eisai that is considered internal or confidential information.
2. Do not publish, post, or release any information or commentary that may be viewed or regarded as Eisai's official view or opinion in any personal social media account.
3. Do not, under any circumstances, engage in any discussion or any activity that may reasonably be interpreted by others as acting on behalf of Eisai. Examples of such activity include, but are not limited to, establishing or operating accounts that include an Eisai name or the names of Eisai-related products and services or using words that imply an association with Eisai; promoting or providing information on Eisai-related products or services; posting content that include copyrighted materials and intellectual property owned by Eisai, e.g., logos, logos in the background of photos, trademarks, advertisements, etc.
4. Do not post or publish any advertisements, or any material that may be construed as advertising or promotion of Eisai's products.
5. Be respectful of others and remember that posting any information or material that is another person's personal information could result in libel, defamation, or discrimination or other claims, which could potentially result in civil or criminal liability for you.
6. Remember that posting any information or material that is considered illegal, inappropriate, or harmful to Eisai, Eisai's employees, clients, business partners or any third party individual or business, could result in claims, which could result in civil or criminal liability against you.
7. Do not post information or material that is, or may be, information or material relating to a competitor's products or services; and
8. Respect intellectual property laws, such as trademark, copyrights, publicity rights, etc., and do not infringe upon the rights of third parties in any photograph, motion picture, video, music, image, painting, text, etc. ("Copyrighted Material"), by downloading, copying, or posting on social media such Copyrighted Material without getting appropriate permission from the owner of such Copyrighted Material.

## 5.5

### Insider information and trading

Insider trading is the buying and selling of securities or other investment products with the knowledge of important facts before announcement, and is prohibited by laws.

The use of important facts for making personal decisions relating to the buying and selling of securities or other investments is illegal. Important facts must be kept strictly confidential and we should not give trading recommendations to those without the information.

Important facts are information that could substantially impact an investor's decision to buy or sell securities (e.g., financial results and forecasts; mergers, acquisitions or joint ventures; and significant strategic and corporate developments, such as clinical trial results or major litigation cases).

#### We should not

- share Eisai's important facts with families, friends, or any third parties; or
- make investment decisions that involve Eisai or other listed company shares for ourselves or anyone else based in any way on important facts.

#### Scenario & Advice



A relative asked me if she should sell Eisai shares, when I knew there would be an announcement soon that would likely have an effect on the share price. Can I tell her what I think she should do?



No. You need to tell her that you can't advise her and that you are not able to share company information.

Code of Conduct

# Part

# 6

## Relationship with society

- 6.1 Human rights
- 6.2 Environmental protection
- 6.3 Tax payments and financial statements
- 6.4 Donations
- 6.5 Organized crime



## 6.1

### Human rights

Eisai has expressed its support for the United Nations Global Compact, a global effort to achieve sustainable growth in the international community. Eisai is committed to upholding internationally recognized human rights wherever our operations are located, and is opposed to modern slavery such as child labor, forced labor, human trafficking, or any other behavior that does not maintain human dignity and respect. This idea is also required of business partners, including suppliers. We need to identify any negative impact on human rights related to our business activities. We should take appropriate action to prevent or mitigate the violation of human rights or to engage in human rights due diligence.

#### We should

- respect the rights of all people in the way we conduct our business.

#### Scenario & Advice



I have become aware that one of our suppliers might be using child labor in their factory. What should I do?



You should inform your superiors, Legal Department, and/or Compliance so that we can investigate, remind them of their obligations under the Eisai Global Code of Conduct for Business Partners and their contracts, and if necessary, terminate the relationship or put additional controls in place.

## 6.2

### Environmental Protection

Eisai considers global environmental protection an important component of business operations and strives to preserve and maintain the environment in compliance with written standards, Eisai's policies and procedures.

Climate change not only threatens human life and livelihoods, but can also hinder the stable supply of pharmaceutical products, which is Eisai's mission, by causing extreme weather events and shutting down factories.

To achieve a sustainable society, Eisai aims to mitigate climate change by reducing greenhouse gas emissions, promote resource recycling through effective use of resources, including water and proper disposal of waste, and conserve biodiversity. We strive to develop business activities that take into consideration the fair use of biological resources.



## 6.3

### Tax payments and financial statements

Eisai must make the correct payments to governments as required by applicable tax laws. For proper tax payments, it is important to maintain sufficient documents to prove and support the accuracy of our records and to establish proper criteria for our decisions. Eisai prohibits false information and forged expense claims in reimbursement and account settlements, as well as misrepresentation or concealment of relevant facts in a tax investigation, all of which hinder proper tax payments.

Because we are a publicly traded company, we are required to establish, develop, and implement internal controls and accurately disclose information about certain types of corporate activity in our annual reports. Accordingly, we must make sure that all our stakeholders receive correct and complete information in a timely manner.

#### We should

- properly document decisions to support information we disclose to tax authorities;
- prepare expense claims promptly and accurately, attaching all relevant documents (i.e., invoices, expense claims), and clarifying the amount and business purpose of the expense; and
- keep proper documentation of approved company spending, and provide complete and accurate documentation upon request by Eisai, its auditors, or the government.

#### We should not

- falsify any company records or take any step to impair the accuracy of Eisai's reports of its business or financial performance.

## 6.4

### Donations

Eisai may make donations that contribute to society. Donations range from medical associations and academic societies involving medical personnel, patient groups, community groups, and non-profit organizations. Such donations must be reviewed and approved in accordance with local regulations and internal procedures.

To ensure transparent decision-making and accountability for all donations, we establish donation rules.



## 6.5

### Organized crime

Eisai does not enter into relationships with organized crime groups, and in the event that we identify such, we sever the relationship.

If it is found that individuals or third parties we work with are involved in, or are suspected of being involved in organized crime, we promptly report our concerns to Compliance.





## Compliance test

We all aim to realize our *hhc* mission. Before you take any action or make any business decision, please ask yourself the following questions to make sure you are in line with our compliance standards. If you are in any doubt, you are encouraged to consult with your superiors. If, for some reason, you cannot consult with your superiors, please contact Compliance.

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**1. Could you openly tell your family what you have done?**

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**2. Do you think it's acceptable to be non-compliant as long as you are not found out?**

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**3. How would it feel to read a report of your activities in the news or on social media?**

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