

hhc & Compliance

Compliance Handbook

Eisai Network Companies

**English
Version**

January 2017

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

The modern pharmaceutical industry has two missions: the discovery and the development of curative medicines and preemptive medicines. Also we make every effort to get access to those medicines for people in need.

To fulfill these missions the fundamental corporate strength we need is compliance. Compliance underpins the basic ability for the growth. But compliance changes as time passes; in other words, it is a living standard. What was right yesterday may no longer be right today. This is the reason we train ourselves constantly through various sessions both internally and externally.

Above all, I would like to emphasise that if you do the wrong thing with regard to modern compliance, the consequences for you as an individual and for the company as an organisation will be devastating. This Compliance Handbook provides guiding principles to help you and Eisai stay compliant and achieve our missions.



January 2017

Haruo Naito

Representative Corporate Officer and CEO

Eisai Co., Ltd.

Haruo Naito

Message from the Chief Compliance Officer

Eisai's ethical standards are focused around its *hhc* philosophy where patients and their families are at the core of what we do, and include integrity, respect and openness. These are central to establishing and maintaining trusting relationships, not only with colleagues, but also with our stakeholders, our business partners, patients, the communities within which we work and those who govern us. They guide us in all we do and with whomever we work.



The continued success of our organisation depends on the ability of each of us to live up to these standards as we navigate the challenges we encounter in our day-to-day activities – not only in the letter, but also in the spirit. This includes full and part time employees as well as anyone representing Eisai.

Every employee has an individual responsibility to work together as a team to meet the standards of behaviour set out in this Handbook. In addition those of us who have managerial responsibilities are required to ensure that our team members are familiar with the contents of this Handbook as well as all the rules, regulations and principles that apply in our business area and to be a role model to them in the way we behave.

We recognise that this Handbook does not cover every compliance situation that we might face in our work. In these situations, we must use our personal judgement to make the right decisions. We must consult others if we are not sure, for example our colleagues, our manager(s) or the Compliance function (“Compliance”).

Compliance encourages everyone to be proud to work for Eisai, to embrace our standards and be passionate in everything we do. If any of you has any concerns or problems, please speak up.

January 2017

Junichi Asatani

Chief Compliance Officer

Eisai Co., Ltd.

A handwritten signature in black ink that reads "Junichi Asatani". The signature is written in a cursive, flowing style.

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Introduction to the Compliance Handbook

A. What is compliance in Eisai?

Compliance in Eisai means complying with written standards such as laws, regulations, Eisai policies and procedures as well as the ethical standards of integrity, respect and openness.

B. Who is this Handbook for?

This Handbook contains Eisai's Charter of Business Conduct and Code of Conduct applicable to anyone working with or on behalf of Eisai, including officers, directors, managers, employees, contractors and agents.

C. What is the purpose of this Handbook?

The Handbook highlights some of the written and ethical standards Eisai expects everyone to comply with. It provides some guiding principles. The Handbook does not give detailed solutions to every situation we face in our day to day activities. We need to refer to Eisai policies and procedures for further information.

The Handbook sets out the available resources everyone can use to support the implementation of these standards. We should discuss matters with colleagues and in particular consult our manager. In addition, we can consult our local or regional Compliance Contact or Helpdesk, Compliance Department ("Compliance"), Human Resources or Legal Department as appropriate.

We must remember that our activities do not necessarily end when we leave our place of work. If we interact with customers, attend professional events or travel on business, we are representing Eisai. The standards outlined in the Code apply to those activities too, and need to be subject to the same judgements we make about our activities as in our place of work.

D. How to use this Handbook

Everyone is expected to read and understand the guiding principles covered in this Handbook and apply them to their day to day activities.

Charter of Business Conduct

Established: March 2000

Revised: January 2017

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 their families under any healthcare system.

It is an integral part of our corporate mission that we exercise good business judgement and act in a proper manner, in compliance with all relevant laws and ethical standards. These principles are essential to the company’s existence and are given top priority in all corporate activities.

We hereby establish our Charter of Business Conduct as a statement of our commitment to compliance. Eisai’s officers, directors and managers recognise that it is their role to lead by example 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.

Eisai and its stakeholders

- We promote mutual respect and trust in our business relationships including healthcare providers, shareholders, investors, employees, business partners, patients and communities
- We do not tolerate bribery or any other form of corrupt business behaviour
- We compete fairly
- We appropriately manage information and ensure our records are accurate, complete, fair and secure
- We communicate with stakeholders, and appropriately disclose corporate information in a timely manner
- We act in accordance with the principles of fairness, respect, and non-discrimination in the workplace and provide a safe work environment for our employees

Eisai and society

- We comply with all relevant laws and regulations of each country in which we do business and we conduct ourselves with the highest level of integrity
- We respect human rights and prevent, within the scope of our business, modern slavery such as child labour, forced labour and human trafficking, while we take into consideration the cultures and customs of the countries where we operate
- We are a “good corporate citizen” and support and encourage activities that contribute to society
- We maintain fair and transparent relations with political and government entities
- We shall not enter into, or to the extent we become aware we shall sever, relations with organised crime groups
- We promote best practices for environmental protection in our business activities

Code of Conduct

Part 1



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

- 1.1 Our responsibilities
- 1.2 Additional responsibilities for officers, directors and managers
- 1.3 Asking questions and reporting compliance concerns

1.1 Our responsibilities

Compliance is everyone's responsibility. Everyone is responsible for being trained on, understanding and applying relevant laws and regulations, Eisai's ethical standards, policies and procedures.

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

Our managers can help us implement the standards set out in this Handbook. We should ask our manager if we have a question or are unsure about how to deal with a situation that we think is not covered 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 our local or regional Compliance Contact or Helpdesk, Compliance Department ("Compliance"), Human Resources or Legal Department, can also help us if our manager is unable to provide clear guidance or we are more comfortable discussing a concern with someone other than our manager.

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

1.2 Additional responsibilities for officers, directors and managers

In addition to the responsibilities described in the previous section (page 10), officers, directors and managers are expected to lead by example when applying relevant laws and regulations, Eisai's ethical standards, policies and procedures to their day to day activities.

Officers, directors and managers must guide and train employees under their supervision and ensure that their employees follow all laws and regulations and Eisai's ethical standards, policies and procedures. They are responsible for helping to implement the compliance programme in their area.

Eisai gives its officers, directors and managers responsibility for the compliance programme, but the Board of Eisai oversees its overall implementation and is responsible for ensuring that appropriate Compliance structures and systems are in place and operating effectively.

Officers, directors and managers are responsible for ensuring that compliance concerns in their area are properly handled and resolved. Prompt and accurate internal reporting about compliance concerns is essential to the success of the compliance programme. The compliance performance of officers, directors and managers is a critical part of their management performance and they are evaluated on that basis.

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

1.3 Asking questions and reporting compliance concerns

It is everyone's responsibility to ensure Eisai complies with laws and regulations, Eisai's ethical standards, policies and procedures. 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 or we become aware of non-compliance, with written and ethical standards we should speak with our manager or consult Compliance, Human Resources, Legal or other relevant departments as appropriate.

Compliance concerns should be reported promptly because the earlier the company knows about them the sooner it can investigate and take appropriate action.

1.3.1 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.

Compliance can help us:

- understand our obligation to report compliance concerns and methods for making a compliance report
- 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 manager, or we do not consider that our manager's advice meets Eisai's standards
- when we report an activity that may not comply with written or ethical standards

Compliance cannot help us:

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

1.3.2 Reporting compliance concerns

You should always report something you believe not to comply with laws and regulations, Eisai's ethical standards, policies or procedures. If you are not sure, you should contact Compliance.

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

Scenario

I think a colleague is engaged in conduct that does not comply with the law as well as Eisai policy but I don't want him to get in trouble. What should I do?

Advice

You should speak to your manager or Compliance rather than ignore a problem which potentially could damage Eisai's business, reputation or patients.

Part 2



Our working environment

2.1 Discrimination

2.2 Harassment

2.3 Health and safety

2.4 Drugs and alcohol

2.5 Use of social media

2.6 Conflicts of interest

2.7 Fraud

2.1 Discrimination

Eisai welcomes and respects diversity, and believes in the fair treatment of all people. All our activities, including recruitment, training, and promotion, reflect that philosophy. Eisai policies are intended to encourage the professional growth and development of all employees in a workplace environment that is free from discrimination.

Examples of discrimination include, but are not limited to: race, gender, age, disability, national origin, religion, sexual orientation, marital status.

In short:

We should:

- treat everyone with respect
- base evaluations of an employee's job performance strictly on the merits

We should not:

- make decisions in respect of any employee or applicant based on attributes not related to the person's job performance or qualifications

2.2 Harassment

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 are all expected to support a harassment free workplace.

We must make a report if we or our colleagues are the victims of harassment. Eisai does not tolerate anyone making sexual advances toward a colleague in the workplace or work-related environment, or taking intimidating or offensive actions that create a hostile working environment.

In short:

We should:

- treat everyone with respect and professionalism and as business colleagues, not social friends or classmates. The workplace is a professional environment, not a home or school or private club

We should not:

- make or use offensive or inappropriate comments, pictures, or written text

Scenario

A colleague tells sexual jokes during the lunch break. What should I do?

Advice

Behaviour or action that makes you uncomfortable and unreasonably interferes 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 behaviour is offensive to you or your colleagues and ask him or her to stop. You may also consult your manager, Compliance, or Human Resources for further guidance.

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 manager or relevant department.

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 or safety of employees, and that are strictly regulated or may impact the environment. If we are involved in these types of activities we should consult our local written standards to understand how to work with these materials or equipment.

The use of certain medicinal drugs may impair our ability to function properly. We should be aware of how this can affect our day to day activities and if this poses a problem for health and safety at work we should consult our manager, Human Resources or other relevant department.

In short:

We should:

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

We should not:

- depart from safety laws, regulations, policies or procedures
- leave accidents and unsafe or potentially dangerous practices without reporting

2.4 Drugs and alcohol

The use of drugs and alcohol can be a serious workplace issue. Not only can their use lead to significant health problems but anyone under the influence of drugs or alcohol can be a hazard to themselves and others. Eisai believes that alcohol and drugs have no place in the workplace, unless required for a medical condition. Eisai does not allow the use of illegal drugs at work. The consumption of alcohol on site without permission is also prohibited.

Drug and alcohol misuse can create a serious health and safety risk for the abuser and for other employees. We should contact our local Human Resources Department if we are concerned about ourselves or colleagues.

In short:

We should:

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

We should not:

- consume alcohol in the workplace without appropriate permission

Scenario

My department wants to hold a celebration for the launch of our new product. We want to serve food and alcoholic beverages. Since it is a celebration, is it OK to have alcohol?

Advice

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.

2.5 Use of social media

We are all responsible for the reputation of Eisai whether during office hours or otherwise. Our actions may adversely affect Eisai's reputation, which can be detrimental to Eisai's business and consequently to patients. In order to protect Eisai's reputation we should be mindful of what we post on social media in a personal capacity and avoid being seen to be acting on behalf of Eisai, or expressing Eisai's official view or opinion.

Any social media accounts created for Eisai business purposes must be properly approved in accordance with Eisai policies and procedures.

In short:

We should:

- avoid being seen to be acting on behalf of Eisai when acting in a personal capacity
- clearly identify our posts as personal, write in the first person and use a personal email address

We should not:

- open social media accounts in a personal capacity that could be interpreted by others as acting on behalf of Eisai (e.g. using an Eisai company name, names of Eisai-related products or services)
- write about Eisai products or competitor products or services
- post information that might be construed in a way that could damage Eisai's reputation, even indirectly. We should not post disparaging, offensive, obscene, discriminatory or defamatory statements about Eisai, its clients, personnel or business partners
- create social media accounts for business purposes without proper approval

Scenario

My mother has recently been taking an Eisai drug and it seems to be working, and I would like to share this goods news to friends via social media. Can I do this?

Advice

No. It is against Eisai policy for you to write about Eisai's products on your personal social media. Only people authorised to post messages about Eisai and its products can do so through Eisai authorised media.

Scenario

I have created a social media account for use between colleagues at work. Is this acceptable?

Advice

No. Only authorised social media for business purpose is permitted. Communication between colleagues for business purposes must be done through authorized and secure media such as e-mails or company telephones.

2.6 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 and creates conflicting loyalties. This conflict may cause us to make a biased business decision that may not be in Eisai's best interests.

In performing our work, a conflict of interest may arise if we have a personal interest in a possible transaction or in a third party with whom Eisai has a business relation, or if we receive a gift or invitation to an event from a business partner.

If we have an actual conflict of interest or there is a potential for the appearance of a conflict of interest we should declare it to our manager so that an appropriate solution can be found, for example, by removing ourselves from any decision about a third party.

Examples of potential conflicts include:

- professional engagements, including third party board memberships
- setting up or being a trustee of a charity which Eisai supports or is asked to support
- accepting cash, gifts or invitations from a business partner
- owning stock in an existing or potential business partner or competitor
- conducting business with a company owned by a family member or friend
- accepting a position with an existing or potential business partner

In short:

We should:

- declare any potential conflicts of interest to our manager

We should not:

- be unduly influenced in our business activities by relationships with close friends and family members

Scenario

I own stock in a company that does business with Eisai, do I have to disclose this information?

Advice

There may be an issue with your owning stock in a company that does business with Eisai and you must disclose this information to your manager. Your ownership of the stock 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 will need to discuss this situation with your manager and Compliance.

2.7 Fraud

Eisai provides guidelines to detect and prevent fraud, misappropriations and other irregularities. Fraud is defined as the intentional, false representation or concealment of a significant fact which leads someone to act upon it to their detriment.

Each officer, director and manager should be familiar with the types of irregularities that might occur within their area of responsibility, and we should all be alert for any indication of irregularity.

2.7.1 Appropriate use of expenses and funds

Appropriate payments and reimbursement of expenses are fundamental to all legitimate business activities. All expense payments should be conducted in transparent processes (cashless payments, etc.) based on facts, and in a timely manner. We must all submit, use and reimburse expenses appropriately in compliance with Eisai procedures (including requirements such as amount limits, use of preferred vendors, etc.).

Research and Development activities are funded not only by internal resources but also by external resources. We must appropriately manage and use Research and Development funds for their intended purpose.

2.7.2 Assuring reliability of research data

In order to assure reliability of research data, we must have adequate mechanisms to address fraudulent conduct in such activities (fabrication, falsification, plagiarism, etc.). We must follow policies and procedures in research divisions in each country where Eisai operates.

If we become aware of fraudulent conduct, we must contact Compliance.

In short:

We should:

- be aware of the types of irregularities or fraudulent conduct that might occur within our area
- report any effort to engage in fraud, negligence or improper manipulation of clinical trial results

We should not:

- request reimbursement of inappropriate expenses

Part 3



Eisai and its stakeholders

- 3.1 Research and development
- 3.2 Manufacturing and distribution
- 3.3 Promotional and non-promotional communication
- 3.4 Adverse events and safety
- 3.5 Interactions with Healthcare Providers
- 3.6 Relations with regulatory and other public agencies

3.1 Research and development

Research and development activities are the basis of Eisai's business and essential to achieving our *hhc* mission. We carry out our research and development activities respecting intellectual property rights (page 51), data integrity (page 25), health and safety (page 18), Healthcare Providers (page 34), clinical trial participants and the scientific community. We engage in research and development activities that comply with all regulations, internationally recognised 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 rights, safety and well-being of trial participants. Freely given informed consent should be obtained from every participant prior to clinical trial participation.

3.1.2 Disclosure of clinical results

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

3.1.3 Handling regulated chemicals and materials

In the process of research and development, we create and handle various chemicals and materials, which are regulated by laws and regulations, Eisai policies and procedures, such as narcotics, anti-hypnotics (and their raw materials), psychopharmaceuticals and other hazardous chemicals.

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).

3.1.4 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 rigour and due consideration is given to the well-being of the animals as well as to the 3R Principles of animal testing:

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

In short:

We should:

- conduct our research and development activities strictly in accordance with Eisai policies and procedures
- take steps, with the Intellectual Property Department, to secure appropriate intellectual property protection for any research and development work Eisai does
- ensure that all clinical data are recorded and reported according to the clinical study plan
- follow Eisai's guidelines on disclosure of results from clinical studies

We should not:

- suppress negative data about a product in development or otherwise attempt to distort the development record
- engage in fraud, negligence or improper manipulation of clinical trial results

3.2 Manufacturing and distribution

Eisai's manufacturing and distribution activities comply with all laws, regulations and internationally recognised standards e.g. Good Manufacturing Practice (GMP).

Eisai manufactures products of high quality to ensure the health and safety of patients. We carry out our manufacturing activities with due regard for health and safety (page 18), and the environment (page 46).

Quality assurance includes production levels (such as intake and handling of raw materials and finished products, including contract manufacturing) and proper storage and handling of the products during distribution.

In short:

We should:

- be aware of and report any diversion or illegal tampering of our products

We should not:

- conduct activities that cause or may cause contamination of production sites, raw materials or finished products

3.3 Promotional and non-promotional communication

As an *hhc* company Eisai strives to create, produce and market innovative products that provide benefits to patients and their families. Our stakeholders have a legitimate interest in our products and the results of our research and development activities.

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.

Off-label and false or misleading promotion and promotion of pre-approved drugs are prohibited as they may raise legal, regulatory and product liability issues. The relevant department must approve the content of any promotional materials, and we must avoid improper promotional activities.

If we are engaged in promotional activities, we are expected to be familiar with the rules governing promotional activities.

In our promotional and non-promotional activities, we interact with Healthcare Providers; the rules governing this kind of interaction are many and complicated and they vary from country to country (page 34).

3.3.1 Advisory board meetings

Advisory boards meetings should be held only to enable Eisai to answer legitimate business questions to which we do not already know the answer and must comply with local or regional written standards. They are therefore by their very nature not promotional.

To be considered a legitimate advisory board:

- the choice and number of participants should stand up to independent scrutiny
- each member should be chosen according to their expertise so that they will be able to contribute meaningfully to the purpose and expected outcomes of the meeting
- the agenda should allow adequate time for discussion

It may be necessary to discuss clinical data about our drugs but only if that information is essential to meet the stated objective of the advisory board meeting. To do otherwise might be disguised promotion or promotion of an unlicensed drug or indication.

Consult Compliance or the relevant department if you are not certain the meeting being organised is an Advisory Board.

In short:

We should:

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

We should not:

- promote our products for any uses that are not authorised
- provide samples outside the scope of applicable laws and regulations

Scenario

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

Advice

Not unless it has been approved by the relevant Eisai department. Sales representatives may use only those documents and materials that the relevant department in your company has reviewed and approved for promotion and advertising. Documents provided solely for training purposes are not to be distributed outside of Eisai.

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.

If any of us becomes aware of an adverse event relating to an Eisai product, we should immediately report it to our local Pharmacovigilance Department in accordance with local standards.

Eisai is responsible for reporting adverse events to governmental or regulatory authorities. If we are not sure how to proceed, we must ask our manager or contact our local Pharmacovigilance Department.

In short:

We should:

- report all adverse events and safety information on marketed products, as well as on products being used in clinical trials, to the appropriate Pharmacovigilance Department
- be familiar with the requirements and procedures for adverse drug event report

We should not:

- ignore or attempt to conceal adverse information about our products

Scenario

A friend of a friend has posted on social media that they felt really unwell after taking an Eisai drug. Do I need to tell anybody?

Advice

Yes. You must report the message you have seen to your Pharmacovigilance Department in accordance with your local procedures.

3.5 Interactions with Healthcare Providers

Collaboration between industry and Healthcare Providers benefits patients. It is a relationship that has delivered numerous innovative medicines and changed the way many diseases impact our lives. Industry and Healthcare Providers collaborate in a range of activities from clinical research, sharing best clinical practice and exchanging information on how new medicines fit in to the patient pathway. Eisai also interacts with Healthcare Organisations/Entities and Patient Groups to implement our *hhc* mission.

In all of these and other interactions, it is important that we ensure that the interactions are in accordance with applicable laws, regulations, and Eisai policies and procedures and that any compensation provided to Healthcare Providers or Organisations/Entities is in accordance with fair market value.

Any discussion of pricing or discounts must be done in accordance with local standards.

3.5.1 Disclosure of payments to Healthcare Providers, Organisations/Entities and Patient Groups

The collaboration Eisai has with its Healthcare Providers, Organisations/Entities and Patient Groups is important to us. We want to ensure that patients and others have confidence that these relationships are open and transparent and this is why Eisai supports the initiatives of the pharmaceutical industry to disclose details of payments and other benefits in kind. We must therefore capture all relevant information so we can comply with local disclosure requirements.

3.5.2 Domestic and international events

When Eisai arranges an event there are written standards that must be taken into consideration. For example, the local rules applicable to the:

- meeting agenda and materials
- internal and regulatory requirements to pre-approve events
- meeting location and venue

- fair market value thresholds
- hospitality and meals thresholds
- disclosure of transfers of value

For international events we must also consider the nationality of the Healthcare Providers and consult with the relevant departments and countries to ensure compliance with various different written standards.

In short:

We should:

- interact with Healthcare Providers or Organisations/Entities only for a legitimate business purpose
- follow the varied local laws, regulations, policies and procedures applicable to interactions with Healthcare Providers, Organisations/Entities or Patient Groups and specific activities
- assure that any compensation provided to Healthcare Providers or Organisations/Entities is in accordance with fair market value for the particular service provided and consistent with any relevant contract with the Healthcare Providers or Organisations/Entities
- report the details of the interaction in accordance with local policies, if required

We should not:

- interact with or provide anything of value to a Healthcare Providers or Organisations/Entities which is or can be perceived as being an improper inducement to prescribe of Eisai's products
- provide anything of value to or on behalf of a guest or family member of a Healthcare Provider
- try to hide or fail to disclose any compensation or value provided to a Healthcare Providers or Organisations/Entities

Scenario

I have invited an expert to speak at one of our sponsored conferences. Eisai has a great relationship with this expert and I would like to show him my appreciation by taking him to a nice restaurant for dinner. Can I do this?

Advice

Even if the purpose is to provide information of a medical/scientific nature or on Eisai products, or if it is in conjunction with an Eisai-sponsored presentation, an expensive restaurant dinner is likely to be considered inappropriate under the relevant country's standards. Please consult Compliance if you have any questions.

3.6 Relations with regulatory and other public agencies

Our pharmaceutical business is regulated by many public agencies in different countries in the world. We must ensure that Eisai has appropriate interactions with all those agencies; those interactions must be accurate, complete, timely and transparent.

In short:

We should:

- be open and transparent in our interactions with public authorities

Part 4



Relationship with society

- 4.1 Corrupt practices and bribery
- 4.2 Fair trade and competition practices
- 4.3 Political contributions
- 4.4 Environmental protection
- 4.5 Organised crime
- 4.6 Human rights

4.1 Corrupt practices and bribery

It is Eisai policy not to tolerate 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 that prohibit bribery, including bribery of public officials or any other individual or organisation. We should remember the definition of public official differs from country to country and that this term may include Healthcare Providers.

We do not offer or promise any payment or item of value to anyone for the purpose of corruptly influencing their decisions in connection with the supply of goods or services to or from Eisai. We should recognise that violation of these laws may result in criminal charges not only against Eisai but individuals as well.

4.1.1 Third party compliance due diligence

We should ensure that third parties acting on our behalf demonstrate the same high standards as Eisai. To allow Eisai to comply with anti-bribery, anti-corruption written standards we carry out appropriate compliance due diligence on third parties prior to engaging with them and provide training to them when required.

In short:

We should:

- follow written standards for dealing with third parties, whether they are public officials or any other individual or organisations.
- obtain approval for all gifts, hospitality and expenses in accordance with local standards
- consult Compliance if we are unsure of our conduct or the laws applying to the countries where we may be conducting business

We should not:

- give, promise or offer anything of value which is or may be perceived as an inducement for improper conduct
- contract with a third party without conducting appropriate due diligence
- fail to investigate any suspicious transactions by a third party acting on behalf of Eisai

Scenario

I plan to contract with a renowned public official Healthcare Provider for a service. She has asked me to contract with a company for this service instead. I am not sure that this company is really necessary for the service; however, I feel it may be hard to reject such a request. May I contract with this company for the service?

Advice

You may contract for services with the individual or the organisation if there is a legitimate business need and if the contract terms are appropriate. If you are unsure of who is in fact providing the service, or unsure about whether the proposed arrangement provides fair value to Eisai and is otherwise appropriate, please consult Compliance.

4.2 Fair trade and competition practices

Eisai's policy is to compete fairly and legitimately and to comply with anti-trust or competition laws in each country in which we operate. Acts or practices of unfair restraint of trade, for example, cartel, price fixing, etc. are prohibited.

We should consult the Legal Department if we have any questions about the application of competition laws to a particular situation.

4.2.1 Dealings with competitors, distributors, customers and suppliers

Formal or informal agreements or understandings with competitors, distributors, customers and suppliers may be prohibited under competition laws. In some cases, even discussion about the sensitive topics listed below may violate those laws.

Therefore any intended interaction involving these sensitive topics by anyone in Eisai with any third party is prohibited, unless the relevant Legal Department has given its advice and prior written approval.

4.2.2 Sensitive topics for competitors

- pricing, costs or profits
- terms or conditions of sale (including credit extensions or information)
- entering or leaving, or allocating with one or more other companies, product, service or geographic markets
- market share or production or sales volume
- decisions to bid or quote or otherwise allocate customers, suppliers or channels of distribution
- whether and how diligently to pursue R&D projects

4.2.3 Sensitive topics for distributors, customers and suppliers

- terms under which a purchaser of our products resells the products (including price or whether the purchaser can resell)
- making transactions dependent on other transactions (such as buying or selling other products or services)
- restricting a third party to manufacture, buy, sell or provide any service to another party

In short:

We should:

- take measures to avoid discussion of sensitive topics with third parties and, if required, remove ourselves from any such contact at the earliest opportunity
- obtain prior written approval from the relevant Legal Department for any agreement or understanding with any third parties about any sensitive topic
- obtain prior Legal Department review of agendas for meetings with competitors (including trade associations or other industry gatherings)
- make sure that business decisions, including those about R&D, manufacturing, pricing, promotion and sales, are based on independent grounds
- report contact with third parties in line with company policy

We should not:

- communicate and agree with third parties about sensitive topics, without prior advice and/or approval from the relevant Legal Department

Scenario

I plan to attend a conference where one of our co-promotion partners will be present. This co-promotion partner has recently introduced a product that competes directly with one of our products. Can I discuss their new product with them?

Advice

You should limit your discussion with co-promotion partners to co-promotion matters. Any conversation about their new product will raise competition law questions, and unless the Legal Department has approved it in advance, you should not discuss the new product with the business partner.

Scenario

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

Advice

Yes, there is. Competition laws don't think markets should be "orderly". Competitors are supposed to make independent business decisions. If they have agreements or understandings with their competitors about sensitive topics, they violate competition laws in the process. Eisai will not tolerate such an outcome, and it exposes the individuals involved, as well as Eisai, to legal liability.

4.3 Political contributions

Donations to politicians and political organisations are regulated in each country. In dealing with political donations, Eisai complies with local laws and regulations.

In short:

We should:

- obtain appropriate internal approvals before making any contributions to politicians or political organisations in the name of Eisai

4.4 Environmental protection

Eisai places global environmental protection as an important component of business operations and strives to maintain the environment in compliance with written standards.

In short:

We should:

- help conserve energy and materials through recycling, power saving, water saving, etc.
- be alert to ways in which Eisai's activities can be changed to reduce the company's environmental footprint

4.5 Organised crime

We do not enter into, or to the extent we become aware we sever, relations with organised crime groups.

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

In short:

We should:

- be aware that organised crime exists
- avoid any situation that could involve Eisai in relations with organised crime

4.6 Human rights

Eisai is committed to uphold all internationally recognised human rights wherever our operations are located. Eisai will not tolerate the use of, including by its third parties or their supply chains, modern slavery such as child labour, forced labour, human trafficking or any other behaviour that does not maintain human dignity and respect.

In short:

We should:

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

Scenario

I have become aware that one of our suppliers regularly uses children to work in their factory. What should I do?

Advice

You should inform your manager and/or Compliance.

Part 5



Corporate assets and information

- 5.1 Documentation
- 5.2 Intellectual property
- 5.3 Confidential information
- 5.4 Protection of personal data
- 5.5 Insider information and trading
- 5.6 Eisai's assets
- 5.7 Tax payments and financial statements

5.1 Documentation

Documents are the memory 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, accurate and thoughtfully prepared so they are not misunderstood later, or taken out of their proper context.

The knowing creation of false documentation, or the improper alteration of documents, makes it impossible rely on the company's memory. Such misconduct is a gross violation of compliance and will be severely punished, up to and including termination from employment.

5.2 Intellectual property

We spend a great deal of time, effort and money developing valuable new products to improve patients' health and quality of life. During the course of this product development, new technology, new designs, and unique product names may be invented or conceived. These may give rise to valuable assets in the form of intellectual property rights such as patent rights, design rights, trademark rights, copyright, know-how, and trade secrets. Others view their own intellectual property rights in the same way and we may not use intellectual property owned by a third party without the third party's permission.

If we are uncertain about Eisai's intellectual property or the steps necessary to protect Eisai's rights, or whether a third party's rights are relevant to our activities, we should consult our manager, the Intellectual Property Department, Legal or Compliance.

5.2.1 Copyright

Whilst patent and trademark rights must be registered if they are to be protected, copyright need not be.

- We must be aware that copying another party's work, even absent any copyright registration, could be considered copyright infringement.
- We should obtain permission from the appropriate copyright holders to use their copyrighted works, and comply with the relevant laws when citing copyrighted works.

In short:

We should:

- be vigilant in the protection of Eisai's own intellectual property and let your manager, Compliance or Legal know if third parties are violating Eisai's rights
- be aware of relevant third party patent and other intellectual property rights
- obtain permission from the appropriate copyright holders to use their copyrighted works, and comply with the relevant laws when citing copyrighted works

We should not:

- disclose (even unintentionally) to anyone outside Eisai any trade secret or know-how that belongs to Eisai
- obtain from someone who joins Eisai, trade secrets or other intellectual property of their previous company

Scenario

Am I allowed to quote from another person's copyrighted work for the purpose of preparing promotional materials?

Advice

In many countries, it is permissible to quote from another person's published work, with appropriate credit to the author. But there are certain requirements you must meet in order to quote the material lawfully. If you fail to meet such requirements, you (and Eisai) may be in violation of copyright laws. Therefore, please consult and seek advice from Compliance or the Legal Department.

Scenario

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?

Advice

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

5.3 Confidential information

5.3.1 Confidential information

Confidential information is an important Eisai asset. Confidential information includes anything from inventions, know-how and research results to financial data and customer lists. Disclosing our confidential information intentionally or accidentally might undermine our business. Therefore, we must make every effort both 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 third parties is similarly important to their success. When we come across information from a third party in our work and everyday life, we are required to obtain the necessary permission to use it.

In all these cases, each of us needs to ensure that information that should stay within Eisai does stay within Eisai because, if it does not, its value to Eisai and perhaps others will be lost or diminished.

5.3.2 Information and Communication Technology security

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

If we become aware of any suspicious activities we should contact our local ICT Department or Compliance.

In short:

We should:

- discuss confidential information only in private locations. Remember that conversations using speaker phones and cellular/mobile phones can be overheard by others
- review confidential documents only in private locations
- when sending facsimiles or e-mails or text or other messages, ensure they are sent only to the proper recipients
- if we need to share confidential information with a third party, get the approval of our manager and the manager responsible for Information Security in advance

We should not:

- discuss confidential information in elevators, hallways, restaurants, airplanes, taxi cabs, trains or any other public places
- dispose of confidential documents in such a way that they might be picked up by others

Scenario

I have a large amount of company data in my computer. Can I take my computer with me to work away from the office?

Advice

If you are permitted to work away from the office (for example, at home), as per local company policy, you must ensure that your computer is securely protected e.g. use of a strong password. Please note that if you take your computer outside the office, you must make sure it is in your possession or in a secure place at all times. Do not leave the computer in your car or any place else that it can be taken by others.

Scenario

If I develop an improvement to an existing product that is not patentable, is this considered confidential information?

Advice

Yes. All discoveries, inventions, improvements, and innovations, regardless of their patentability, are considered to be valuable or confidential information and should not be shared with anyone outside Eisai without the necessary approval.

5.4 Protection of personal data

In the course of its business, Eisai has personal information about its employees, patients, Healthcare Providers, suppliers, customers and contractors. Personal information is any information that identifies a living individual. Examples include lists of employees, and records that show their birth date, government-issued identification number or other identifying information or medical information.

Eisai is committed to complying with data protection laws around the world. Some data protection laws specifically control how personal information can be used by organisations and businesses.

Eisai is responsible for using data in accordance with applicable data protection principles to ensure that such data are, at a minimum,

- used fairly and lawfully
- used for limited, specifically stated purposes
- used in a way that is adequate, relevant and not excessive
- accurate
- kept for no longer than is absolutely necessary
- handled according to people's data protection rights
- kept safe and secure
- not transferred to other countries without adequate protection

There is often stronger legal protection for data which is deemed sensitive personal information.

In short:

We should:

- Access an individual's personal information only with permission and when a clear business need exists, and in accordance with applicable law
- Share personal information only with someone who has permission and a need to know the information
- Be aware of all local laws and regulations regarding personal data protection when transferring or receiving personal data across countries and regions

We should not:

- Use or disclose anyone's personal information for any purpose other than the one for which it was collected
- Distribute any personal information without being sure that the distribution is allowed by applicable law

5.5 Insider information and trading

Insider information is information that is not public and that an investor would consider important (“Material Information”) when deciding whether to buy, sell or hold stock. The use of insider information for making personal decisions relating to the purchase or sale of securities or other investments is illegal. Insider information must be kept strictly confidential and we should not give trading recommendations to those without the information.

Examples of material Information include: financial results and forecasts; changes in dividends; possible mergers, acquisitions or joint ventures; and significant strategic and corporate developments, such as R&D or clinical trial results, major litigation developments, that are not yet public.

In short:

We should:

- keep Eisai insider information confidential and use it only for the business purposes for which it was developed

We should not:

- share Eisai insider information with family, friends or any other third party
- make investment decisions for ourselves or anyone else that involve Eisai or other listed company shares and that are based in any way on insider information

Scenario

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?

Advice

No. You need to tell her that you can't advise her and you can't give her information or hints about what is going on.

5.6 Eisai's assets

Protecting Eisai's assets is important. Eisai's assets include items such as computers, telephones, lab equipment, office supplies, and company products, as well as intangible assets such as intellectual property rights. Any loss, theft or improper use of these assets can cause serious financial loss and damage to Eisai's business.

In short:

We should:

- take all appropriate steps to protect Eisai's assets and report any loss or theft immediately

5.7 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 or account settlements, as well as misrepresentation or concealment of relevant facts in a tax inspection; all these activities hinder proper tax payments.

As we are a publicly traded company we are required to disclose information about certain types of corporate activities in our annual reports. Accordingly, we must make sure that all our stakeholders receive correct and complete information in a timely manner.

In short:

We should:

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

We should not:

- falsify expense claims
- falsify any company record or take any step to impair the accuracy of Eisai's reporting of its business or financial performance

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 your manager. If, for some reason, you cannot consult your manager, please contact Compliance.

- Could you openly tell your family what you have done?
- Do you think it's acceptable to be non-compliant as long as you are not found out?
- How would it feel to read a report of your activities in the news or on social media?

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