Compliance Global Policy

Chapter 1　General Provisions

Article 1 (Purpose)

The purpose of this Policy is to strive to maintain legal and regulatory compliance and a fair relationship with society as set forth in the "Ono Group Code of Conduct," define a framework for compliance management, and promote compliance of Ono Group.

Article 2 (Definitions)

The terms used in this Policy are as defined below.

(1) OPJP means Ono Pharmaceutical Co., Ltd.
(2) Ono Group means Ono Pharmaceutical Co., Ltd. and its consolidated subsidiaries.
(3) Affiliated Companies mean consolidated subsidiaries of Ono Pharmaceutical Co., Ltd.
(4) Employees, etc. mean officers and employees of each company and other persons who are under the control and direction of each company.
(5) Departments mean overall organizations such as divisions and departments to which the persons described in this Policy belong.

Article 3 (Scope and Responsibilities)

This Policy applies to Ono Group companies as well as all Employees, etc. thereof.

In accord with this Policy, each Ono Group company is responsible for promoting compliance management that is consistent across the Group and establishing a system for this purpose.

2. In fulfilling the responsibilities specified in the preceding paragraph, each Ono Group company shall prepare a compliance policy that is consistent with this Policy and is appropriate to the circumstances of each company or country.

Chapter 2　Compliance Management Basic Guidelines

Article 4 (Definition of the Compliance Management Basic Guidelines)

For the purpose of showing reference for practicing "Ono Group Code of Conduct," the "Compliance Management Basic Guidelines" is established as shown in Appendix 1.

Chapter 3　Compliance Program

Article 5 (Compliance-based Management)

In corporate management, companies are required to fulfill social responsibilities including establishment of a governance system, securing of transparency of corporate management, protection of consumers, and consideration for environment and society, and also to ensure compliance as a premise thereof.

Ono Group is required to adhere to higher ethical standards because it handles products related to human health. Its pharmaceutical division, which is the core business of the Group, has contacts with officials of related governmental agencies in related countries, including the Ministry of Health, Labor and Welfare in Japan, and public servants etc., of public institutions, including doctors and employees thereof, in various scenes, such as drug discovery research, clinical trials, manufacturing and marketing, and provision of product information. These contacts are based on the relationship between the applicant and authorizer in an application for license or authorization, between the sponsor and contractor in drug discovery research or a clinical trial, or between the manufacturer and purchaser of a pharmaceutical product, providing a potential risk for unfair relationship and potentially causing major issues in compliance.

Ono Group positions compliance as a pillar of its corporate management and will operate its business with the mindset that no Employee, etc. will violate compliance.

Article 6 (Compliance Program)

In order to promote the mindset that no Employee, etc. will violate compliance, it is important to follow the PDCA cycle (Plan=formulate a plan to ensure compliance, Do=implement the plan, Check=examine the status of implementation carefully to identify problems in the plan, Action=correct problems, if any) to make continuous improvements.

The organizational structure and mechanism for following the PDCA cycle to promote compliance in the Ono Group

are defined as the "Compliance Program."

Article 7 (Organizational Structure and Mechanism of Compliance Program)

The organizational structure and mechanism of the Compliance Program are specified in Paragraphs 2 through 14 of this Article.

The conceptual diagram of relationship is presented in Appendix 2. The details shall be separately specified in the compliance policies of the Ono Group companies.

Organizational structure:	Board of Directors, Management Meeting, Corporate Officer in charge of Compliance, Group Compliance Committee, Compliance Committee, Compliance Supervisory Department, etc., Compliance Promotion Lead, Compliance Promotion Manager, compliance managers, auditors (Board of Auditors)
Mechanism:	Policy establishment, training and enlightenment, whistle-blowing system, consultation system, third party management, risk assessment, audit by internal audit division

(Organizational Structure)

2. Board of Directors

OPJP Board of Directors shall make decisions on important matters pertaining to the establishment of organizational structure or mechanism of Compliance Program. It shall receive reports from the Corporate Officer in charge of Compliance and take necessary measures according to the contents thereof.

Affiliated Companies shall examine the involvement of the Board of Directors on compliance which is specific to each company on the basis of the situation of each company, laws and regulations of local authorities, etc.

3. Management Meeting

OPJP Management Meeting shall deliberate the appropriateness of the contents of the matters subject to the resolution of the Board of Directors before they are presented to the Board of Directors.

For Affiliated Companies, if the Management Meeting is established, the involvement of the Management Meeting for compliance specific to each company shall be examined based on the situation of each company and laws and regulations of each country.

4. Corporate Officer in Charge of Compliance

In order to promote compliance in Ono Group, a Corporate Officer in charge of Compliance shall be appointed in OPJP. Corporate Officer in charge of Compliance shall supervise the proper establishment and operation of the Compliance Program of the Ono Group as a whole, make decisions on individual matters in the operation of the Compliance Program, and operate the Group Compliance Committee.

Affiliated Companies shall examine the necessity of appointment of a Corporate Officer in charge of Compliance which is specific to each company on the basis of the situation of each company, laws and regulations of local authorities, etc.

5. Group Compliance Committee, Compliance Committee

The Group Compliance Committee shall be established in OPJP to deliberate and make decisions on matters related to the establishment and operation of Compliance Program in the Ono Group. The Committee shall conduct substantive and thorough discussions by addressing important individual matters and matters reported or shared from Affiliated Companies as agendas, in addition to deliberation on matters relating to activity policies and annual plans including compliance-related systems, important changes in policies, for training, etc.

Affiliated Companies shall examine the necessity of establishment of a compliance committee or decision-making meeting equivalent thereto which is specific to each company on the basis of the situation of each company, laws and regulations of local authorities, etc.

6. Compliance Supervisory Department, etc.

OPJP shall position its Risk & Compliance Management Department as the Compliance Supervisory Department, etc., which has a function of supervising the activities related to the development and operation of the Compliance Programs within Ono Group under the supervision of the Corporate Officer in charge of Compliance, and centrally manage compliance-related tasks.

Affiliated Companies shall establish a Compliance Supervisory Department, etc. while paying attention to independence from business promotion divisions including sales. The Compliance Supervisory Departments, etc. may include any section, team or individual that belongs to an Affiliated Company depending on its organizational structure.

7. Compliance Promotion Lead, Compliance Promotion Manager, Compliance Manager

Since most of compliance issues occur in workplaces, it is required to ensure to conduct compliance management activities in each workplace.

OPJP shall appoint a Compliance Promotion Lead in each division and Medical Affairs, Compliance Promotion Manager in each Affiliated Department and a compliance manager for each workplace.

The Compliance Promotion Lead shall supervise the status of compliance management activities as the responsible person for compliance management activities in each division or Medical Affairs, and take responsibility for compliance management activities in each division or Medical Affairs in cooperation with Compliance Promotion Manager, compliance managers, workplace heads, Risk & Compliance Management Department, etc.

Compliance Promotion Manager shall assist the Compliance Promotion Lead, and lead compliance management activities in the Affiliated Department in cooperation with compliance managers, Risk & Compliance Management Department, etc.

Compliance manager shall, as a consultation desk to listen to the voices of Employees, etc. related to compliance at each workplace, deliver their voices to the head of the workplace, Compliance Promotion Lead, Compliance Promotion Manager, Risk & Compliance Management Department, etc. In addition, compliance manager shall promote on taking ownership of compliance at the workplace and assist in response to compliance-related risks.

Affiliated Companies shall examine the necessity of appointment of a Compliance Promotion Lead, Compliance Promotion Manager, compliance manager on the basis of the situation of each company, laws and regulations of local authorities, etc.

8. Auditors (Board of Auditors)

OPJP Auditors (Board of Auditors) shall audit compliance promotion and provide necessary guidance for improvement. OPJP Auditors (Board of Auditors) shall also receive reports from the Group Compliance Committee and give necessary opinions and advice according to the contents thereof.

At Affiliated Companies, OPJP auditors (Board of Auditors) shall examine their involvement in compliance matters which are specific to each company on the basis of the situation of each company, laws and regulations of local authorities, etc.

(Mechanism)

9. Policy Establishment

Each Ono Group company shall establish Policies, SOPs, etc., suitable for the circumstances of each company or country based on the Compliance Management Basic Guidelines. In doing so, Affiliated Companies shall also refer to various policies of the Group established by OPJP, including global policies.

10. Training and Enlightenment

Each Ono Group company shall formulate an annual plan to implement training and enlightenment activities on compliance for its Employees, etc. The Compliance Supervisory Department, etc. shall organize annual plans for compliance training and enlightenment activities.

In compliance training and enlightenment activities, it is important to consider the meaning of the company's business activities and our role within the context of relationship with society so that the corporate mission, which embodies the reason for existence of the company, and "Ono Group Code of Conduct" are integrated into activities of Employees, etc. In this context, sharing the sense of being a member of society, or having the same "aspiration," will be a driving force for "acting better" including compliance for laws and regulations and ethics.

When designing compliance training, an attention shall be paid to: 1) identifying trainees by hierarchy, organization, etc., and sharing the philosophy of the organization, 2) having them learn the habit of ethical thinking, 3) having them understand specific knowledge about related laws, regulations, etc., and environmental changes so that the learned knowledge can be used in real situations.

In addition to compliance training, periodic enlightenment activities by offering information through intranet, etc., shall be implemented.

11. Whistle-blowing system and consultation system

When a compliance issue occurs in a workplace, the information will generally be passed through the usual route of reporting, communication, and consultation in the same manner as for other issues in the workplace. Therefore, creation of a well-ventilated workplace is important.

However, compliance issues involving supervisors in the workplace, may be difficult to be conveyed with this usual route. For this reason, each Ono Group company shall establish and operate a whistle-blowing system and a

consultation system as a mechanism to identify concerns about compliance raised by Employees, etc. and to enable reporting or consultation on compliance issues directly to the Compliance Supervisory Department, etc.

12. Third Party Management

Compliance issues which occur at third parties such as business partners and contractors of Ono Group may even affect the Group.

Each Ono Group company shall, with the involvement of the Compliance Supervisory Department, etc., manage third parties focusing on check on the compliance system, presence or absence of violation cases, etc., of the other party when starting transactions, or during transactions, if necessary.

13. Risk Assessment

The environment surrounding us and laws, regulations, etc., changes with the times. We are thus required to strengthen and improve the organizational structure and mechanism in the Compliance Program according to risk assessment where necessary.

Under the direction of the Corporate Officer in charge of Compliance, the Compliance Supervisory Department, etc. of each Ono Group company shall conduct risk assessment by utilizing surveys on the awareness of Employees, etc. on compliance, hearings to determine compliance risks, questionnaires, etc., verify whether there are any compliance problems or issues, and examine and implement strengthening measures and improvement measures where necessary.

14. Audit by Internal Audit Department

Basically, mainly, the Corporate Officer in charge of Compliance, Group Compliance Committee, Compliance Committee, Compliance Supervisory Department, etc., Compliance Promotion Lead, Compliance Promotion Manager, and compliance managers shall check the appropriateness of compliance measures taken by each Ono Group company for compliance in the course of their compliance-related activities, and make improvements where necessary.

There may be problems unnoticed by them. With this in mind, the status of the development and operation of compliance programs at Ono Group companies shall be subject to auditor's or the internal audit division's audits.

Article 8 (Response to Violation and Thorough Prevention of Recurrence)

If any violation of related laws, regulations, etc., notifications, etc., voluntary industry codes, or internal rules is found as a result of internal investigation, whistle-blowing system, consultation system or audit, etc., Compliance Program will become a dead letter and the awareness on compliance will not be ensured unless such violation is strictly and fairly handled by the company.

If any violating case is found, the Compliance Supervisory Department, etc. of each Ono Group company shall thoroughly investigate the fact and cause in cooperation with the relevant department where necessary, and ask the relevant department to take necessary response for the company, such as prompt correction of the violation case, disciplinary action for relevant parties, and recurrence prevention measures, based on the investigated fact.

The Compliance Supervisory Department, etc. of each Ono Group company shall manage the progress of recurrence prevention measures and verify the extent of utilization, effectiveness, etc., of such measures through related audits.

(Examples of recurrence prevention measures)

- Verification of decision-making system, reconsideration of policies, SOPs, etc.
- Review of the system to consult when issues occur
- Review of procedure and approval process (whether sufficient checking function by the supervisor and managing division is effective)
- Review of personnel evaluation system (whether compliance is sufficiently reflected in the evaluation and rating)
- Review of education and training system for compliance (for example, continuous implementation of education on corporate ethics and education on individual laws, regulations, and internal rules)

Chapter 4　Prior Consultation, Reporting, etc.

Article 9 (Framework for Prior Consultation and Reporting)

For the purpose of Appendix 3 to this Policy, "Prior Consultation" refers to consultation and discussion with the Risk & Compliance Management Department of OPJP on matters necessary for the establishment and operation of Compliance Programs prior to implementation.

2. For the purpose of Appendix 3 to this Policy, "Reporting" refers to reporting to the Risk & Compliance Management Department of OPJP on compliance issues that have occurred and other compliance-related activities.

3. The responsible persons in headquarters, supervisory departments, and directly managed divisions of OPJP and the presidents of Affiliated Companies shall consult in advance about or report in accordance with the provisions of Appendix 3 with or to the Risk & Compliance Management Department of OPJP. Where necessary, these matters shall also be reported to the reporting destinations specified in the "Incident Response Manual."

4. The Senior Director of Risk & Compliance Management Department of OPJP shall present and report prior consultation or reports made pursuant to Paragraph 3 of this Article to the Board of Directors, Management Meeting, Corporate Officer in charge of Compliance, Group Compliance Committee, Board of Auditors, etc. within OPJP in accordance with the provisions of this Policy, OPJP Compliance Policy, Corporate Management Global Policy, etc., in accordance with predetermined routes and standards.

5. The items, frequencies, etc., of "Prior Consultation" and "Reporting" are specified as shown in Appendix 3.

Article 10 (Roles of Affiliated Companies and OPJP)

The relevant parties shall assume the roles specified Paragraph 2 and thereafter in this Article in the Prior Consultation and Reporting specified in Article 9.

2. Affiliated Companies are obliged to conduct Prior Consultation and Reporting specified in Article 9, Paragraph 3 even if there is no provision in their own policies, unless it would violate local laws and regulations. If it would violate local laws and regulations, they shall discuss measures to be taken to reach agreement with the Risk & Compliance Management Department of OPJP.

3. Under the direction of the Corporate Officer in charge of Compliance, the Risk & Compliance Management Department of OPJP is responsible for drawing conclusions and communicating results or response policy on matters the responsible persons in headquarters, supervisory departments, and directly managed divisions of OPJP and the presidents of Affiliated Companies consulted about in advance as soon as possible, and providing guidance and advice on reported matters, etc., where necessary.

Supplementary Provisions

For revision and abolition of this Policy, a request for managerial decision shall be made after deliberation and approval of the Board of Directors. The approver of request for managerial decision shall follow the provisions of the Policy Management Policy.

2. This Policy will be enacted on March 28, 2023 and become effective on the same day.

Appendix 1 Compliance Management Basic Guidelines
Appendix 2 Conceptual Diagram
Appendix 3 List of Matters for Prior Consultation or Reporting

Appendix 1 Compliance Management Basic Guidelines

1. Basic Stance
2. Drug Discovery Research
3. Clinical Trial
4. Application for Approval
5. Post-marketing Safety Management, Surveillance, etc.
6. Clinical Research
7. Supply Chain
8. Environmental Conservation
9. Interactions with Healthcare Professionals (Medical Information Activities, etc.)
10. Corporate Communication Activities
11. Participation in Society and Contribution to its Development
12. Relationship with Patient Groups
13. Relationship with Public Servants, etc.
14. Relationship with Politics and the Government
15. Outsourcing to Healthcare Professionals, etc.
16. Donation, etc.
17. Sponsorship, etc.
18. Prohibition of Unfair Transactions
19. Management of Conflict of Interest
20. Response to Anti-social Forces
21. Respect for Human Rights
22. Pleasant Working Environment
23. Fair and Transparent Personnel Affairs
24. Prohibition of Private Use of Company Assets
25. Internal Control
26. Handling of Intellectual Property Rights and Compliance with Policy for Invention during business
27. Handling of Confidential Information and Respect for Confidential Information of Third Parties
28. Protection of Personal Information
29. Insider Trading Regulations, etc.
30. Whistle-blowing
31. Response to International Standards and Overseas Laws and Regulations and Contribution to Local Societies

* Related laws, regulations, etc. in this Appendix 1 includes "notifications," "voluntary industry codes," etc. in this Appendix 1.

1. Basic Stance

[1] When we act, we will not only abide by the laws and regulations, but also adhere to high moral values including life ethics, as personnel of a life science company which trades products that serve to the health of people.

[2] We will always prioritize actions based on high moral values regardless of "business considerations," and will not pursue profits as a company or accomplishments as an individual.

[3] We will realize that we assume the final responsibility even for a task, a part of which is outsourced to a contractor, in various stages of research, development, manufacture, sales, etc., of products. Therefore, we will explain our stance, etc., to the contractor to perform the task with a sense of unity.

2. Drug Discovery Research

[1] We will always check whether substances synthesized or obtained externally in the processes of drug discovery research are poisonous/deleterious/radioactive substances, narcotics, psychotropics, psychostimulants, etc., that are regulated by laws and regulations, and take actions in accordance with such related laws, regulations, etc.

[2] When we use genes, tissues, etc., collected from human bodies, we will take all possible measures to protect the personal information in compliance with related laws, regulations, etc., as well as relevant internal rules. In gene modification experiments, we will comply with related laws, regulations, etc., and ensure safety management to prevent gene-modified organisms, etc., from affecting wild animals, plants, etc.

[3] We will comply with related laws, regulations, etc., to prevent biohazard accidents caused by pathogens, etc.

[4] When we conduct animal experiments, we will comply with related laws, regulations, etc., and internal rules, while respecting the lives of animals, using animals as minimally as possible, and making efforts to avoid inflicting suffering as far as possible. We will also consider the development of and switching to alternative methods.

3. Clinical Trial

[1] In conducting a clinical trial, we will comply with related laws, regulations, etc., and internal rules. We will also thoroughly discuss whether the drug is worth conducting a clinical trial for, with data obtained from research and development.

[2] In conducting a clinical trial, we will respect the human rights of the subjects of clinical trials to the maximum extent possible. We will provide necessary information to medical institutions appropriately. If it is determined that there is a safety problem, the plan is reviewed immediately to judge the appropriateness of the continuation of the clinical trial. We will also prepare for any health damage that may occur in subjects in every clinical trial we conduct.

[3] In conducting a clinical trial, we will prepare objective and accurate data on the efficacy and safety of drugs, etc., and will never engage in unfair practices such as the falsification, replacement, concealment, etc., of data. We will not require such unfair practices of contractors, joint research institutions, etc.

[4] We will appropriately disclose clinical trial information and information on expenses and funding to conduct clinical trials in accordance with related laws, regulations, etc., to improve transparency.

4. Application for Approval

[1] When we apply for pharmaceutical Manufacturing, Marketing, Approval (including partial change approval application and minor change notification), we will use application data that are prepared accurately based on the results obtained from the surveys or studies conducted in compliance with related laws, regulations, etc., and internal rules.

[2] In cases where we get any survey or study results, etc., that doubt the quality, efficacy, or safety of a drug applied, we will also examine and evaluate them and describe the results in the application materials without any unfair practices such as the falsification, replacement, or concealment, etc., of the materials.

[3] If such studies, etc. stated in the preceding paragraph, are conducted by group companies or contractors, we will adequately supervise the implementation of the studies, etc., to ensure that the implementation of the studies, etc., and the acquisition of data are conducted appropriately.

5. Post-marketing Safety Management, Surveillance, etc.

[1] In order to establish the proper use of drugs after marketing, we will conduct post-marketing safety management operations, post-marketing surveillance, etc., in compliance with related laws, regulations, etc., and internal rules.

[2] If we suspect that any adverse event caused by our products has occurred, we will promptly report it to the authorities in accordance with related laws, regulations, etc., and internal rules and take safety assurance measures as necessary.

[3] We will conduct post-marketing surveillance in compliance with related laws, regulations, etc., and internal rules for the collection and preparation of the re-examination or re-evaluation data and as pharmacovigilance activities for drugs, etc.

6. Clinical Research

[1] In support of clinical research, we will comply with related laws, regulations, etc. In doing so, we will fully examine the value of supporting clinical research based on data obtained from extant research and development.

[2] We will pay attention to conflicts of interest, disclose information on funding, and improve transparency in accordance with related laws, regulations, etc.

7. Supply Chain

[1] We recognize that our products can extend life so we will provide a stable supply of approved products to medical institutions and patients in a timely and appropriate manner.

[2] In the manufacture of our products, we will comply with related laws, regulations, etc., and internal rules, conduct appropriate manufacturing and quality control throughout the entire manufacturing process including processes at contract manufacturers, and strive to perform safe operations without causing accidents or disasters. If there is any problem in the manufacturing and quality of drugs, we will take appropriate measures while placing maximum priority on human life, and promptly make every effort to investigate the cause and prevent recurrence.

[3] We carry out logistics and import/export of raw materials, products, facilities, equipment, software, etc., properly in compliance with related laws, regulations, etc., and internal rules.

[4] We will handle raw materials, etc., used to manufacture products in compliance with related laws, regulations, etc., and internal rules, and take appropriate measures in consideration of the impact on the health of Employees, etc. in the manufacturing processes and on the environment because of external discharge.

8. Environmental Conservation

We will conduct business activities in compliance with related laws, regulations, etc., and will always pay attention to the impacts of such business activities on the global environment and environments of local societies as a life science company.

9. Interactions with Healthcare Professionals (Medical Information Activities, etc.)

[1] In interacting with healthcare professionals (medical information activities, etc., for medical institutions, etc.), we will conduct activities with fairness and transparency in compliance with related laws, regulations, etc.

[2] We will acquire the medical and pharmaceutical knowledge which is necessary for interacting with healthcare professionals and provide information on drugs, etc., appropriately to improve and promote the health of patients and general consumers in accordance with related laws, regulations, etc.

[3] We provide information on products to healthcare professionals within the scope of manufacturing sales approval.

[4] In relationships with physicians, pharmacists, etc., at medical institutions that belong to organizations regarded as public servants or deemed public servants (independent administrative corporations in Japan, etc.), we will maintain a healthy relationship so as not to violate or be suspected of violating related laws,

regulations, etc.

10. Corporate Communication Activities

[1] We will disclose corporate information that society needs in a timely and appropriate manner, listen to the opinions of society, and communicate with it.

[2] We will provide information on websites and digital communications using social media, etc., in compliance with related laws, regulations, etc., and internal rules, so that such communications shall not result in advertisements of ethical drugs for people other than healthcare professionals.

11. Participation in Society and Contribution to its Development

[1] We will gain mutual trust with stakeholders around us through activities that take the characteristics of the local community such as culture, religion, tradition, etc., into account.

[2] In promoting social contribution activities, we will identify social issues that we prioritize and management resources that we can invest based on our management philosophy, etc.

[3] We will cooperate and collaborate with a wide range of stakeholders such as NPOs, NGOs, local communities, governments, etc., to contribute to the development of society.

[4] We will support the volunteer activities by Employees, etc.

12. Relationship with Patient Groups

[1] We will have high ethical standards and respect the independence of patient groups in all collaborations with such groups. We will make efforts to understand the purpose and contents of such collaborations with patient groups in full.

[2] We will ensure transparency and improve the reliability of financial support provided to patient groups to gain a broad understanding that the support contributes to the activities and development of patient groups.

13. Relationship with Public Servants, etc.

We will not provide, apply for, or promise illegal money, goods, etc., to any public servant (including deemed public servant) in Japan and foreign public servant. Even if we are asked to provide illegal money, goods, etc., we will decline it with a firm attitude.

14. Relationship with Politics and the Government

[1] We will strive to create appropriate and transparent relationships with politics and the government.

[2] We will make the payment of money to political parties, politicians, political groups, etc., fairly, regardless of the purpose, and comply with related laws, regulations, etc.

15. Outsourcing to Healthcare Professionals, etc.

When we entrust the services of a consultant, advisor, etc., to healthcare professionals and other experts, we will make sure to conclude a written contract, taking care not to violate related laws, regulations, etc. Consultant fees, advisor fees, etc., shall be an amount compatible with the services that we receive, and the contents of the services shall be recorded in writing. If the organization to which the other party belongs has internal regulations related to the roles of consultant, advisor, etc., the regulations shall be complied with.

16. Donation, etc.

When we make donations or grants to medical institutions, universities, external organizations, etc., we must confirm that they are not illegal and make them as either pure donations or grants without requiring the other party for a return and without using them as a means to induce transactions.

17. Sponsorship, etc.

When a symposium, academic conference, scientific or professional meeting or other event targeted at healthcare professionals, patient groups, etc., is to be held under our sponsorship, we will ensure that the event is with an

appropriate purpose and carried out in compliance with related laws, regulations, etc.

18. Prohibition of Unfair Transactions

In relationships with medical institutions, competitors, distributors, and suppliers, we will conduct fair transactions in accordance with related laws, regulations, etc. (competition laws, anti-trust laws, etc.).

19. Management of Conflict of Interest

[1] In situations where the interests of the company come in conflict with the personal interests of Employees, etc., we will prioritize the interests of the company. If a conflict of interests may occur, we will consult with the company and follow its instruction.

[2] We will make the relationship with suppliers, business partners, users, etc., fair and healthy. We will not receive or demand illegal or unfair provision of profits (money, goods, entertainment, benefits, etc.) with respect to job positions or authority.

20. Response to Anti-social Forces

We will not have any relationship with anti-social forces that threaten the order or safety of society (corporate racketeer, organized crime group, etc., in Japan), and firmly confront them without bowing to their unjustified demands.

21. Respect for Human Rights

[1] We understand and respect human rights, various philosophies, personalities, and characters of Employees, etc. as well as of third parties.

[2] We will not discriminate against or harass people on grounds of race, nationality, ethnicity, religion, philosophy, ideology, gender, age, sexual orientation/self-recognition, social status, disability, appearance, education, or any protected category.

[3] We will not allow harassment in the workplace and will strive to respect the personality of workers and create a pleasant working environment.

[4] We will also express our stance including respect for human rights to the supply chain and obtain their agreement.

22. Pleasant Working Environment

We will comply with labor-related laws, regulations, etc. We will also create a working environment with due consideration for safety and health and a flexible working environment to prevent operational accidents and to maintain the health of Employees, etc.

23. Fair and Transparent Personnel Affairs

We will comply with related laws, regulations, etc., and internal rules to promote appropriate job assignment and personnel exchange and conduct fair and transparent personnel evaluation. We will not make any discrimination in staffing, personnel evaluation, or promotion.

24. Prohibition of Private Use of Company Assets

[1] We will use the funds, goods, and other properties of the company only for the business operations of the company, and will not use them for the benefit of individuals or third parties.

[2] We will effectively utilize our information systems and equipment, and will not use them for the benefit of individuals or third parties.

25. Internal Control

[1] We will accurately record our business activities in preparing, creating, and storing accounting records and documents for submissions to government authorities.

[2] We will implement the maintenance and operation of internal controls soundly to ensure the effectiveness and efficiency of business operations, reliability of financial reports, compliance with laws and regulations,

and the preservation of assets.

[3] We will not conduct any acts such as fraudulent accounting, window dressing, etc., and comply with related laws, regulations, etc., and pay taxes properly.

26. Handling of Intellectual Property Rights and Compliance with Policy for Invention during business

[1] We recognize the importance of intellectual property rights and will strive to utilize the results of research and development lawfully.

[2] We will respect the intellectual property rights of not only our company but also of third parties, and do not infringe the intellectual property rights of third parties.

[3] We will appropriately protect service invention of Employees, etc. and promote R&D activities.

27. Handling of Confidential Information and Respect for Confidential Information of Third Parties

[1] We recognize the importance of confidential information collected through our business activities and will manage such information appropriately.

[2] We respect the confidential information of third parties, such as other companies and organizations, and will not obtain, use, or disclose it unfairly. We will not disclose within the company or use for the company confidential information of third parties obtained before joining the company and through temporary transfer to other companies, etc.

[3] We recognize that confidential information stored as electronic information has the same value as such information stored in written format and will manage it properly.

[4] We will not use confidential information of the company or other companies for self-interest or interests of third parties misappropriately.

28. Protection of Personal Information

[1] We recognize the importance of the protection of personal information and will comply with related laws, regulations, etc. We will properly establish and operate a compliance system for personal information protection, such as the promotion of personal information protection, prevention of leakage of personal information, etc.

[2] We will also take necessary and appropriate measures such as the appropriate acquisition of personal information, notification and disclosure of the purpose of use, prohibition of unintended use, safety control measures, education for Employees, etc., restriction on provision to third parties, maintenance and operation of procedures to respond to requests for disclosure of retained personal data, etc.

29. Insider Trading Regulations, etc.

[1] We will comply with the insider trading regulations stipulated in related laws, regulations, etc. When we learn about unpublicized important facts regarding business operations of the Parent company, Affiliated Companies, business partners, etc., (hereinafter "Internal Information") in relation to our duties, etc., we will not transact stocks, etc., of these companies as individuals or as the company unless and until it is published through a certain procedure.

[2] In addition, officers must comply with the regulations on transactions of treasury stock by officers stipulated in related laws, regulations, etc.

[3] We will strictly manage internal information obtained through our duties, etc., and will not communicate such information or recommend transactions to third parties unless it is necessary for our duties.

30. Whistle-blowing

[1] If we find any violation or suspected violation of related laws, regulations, etc., in Japan and overseas or internal rules, we will promptly report it to the company.

[2] If we receive inquiries, consultations, and internal reports on violations or suspected violations of domestic and overseas related laws, regulations, etc., or internal rules, we will respond to them appropriately. We will not treat these persons unfavorably because of their inquiries, consultations, or notifications.

[3] We will sincerely respond to whistle-blowing or inquiries/consultations regarding whistle-blowing from

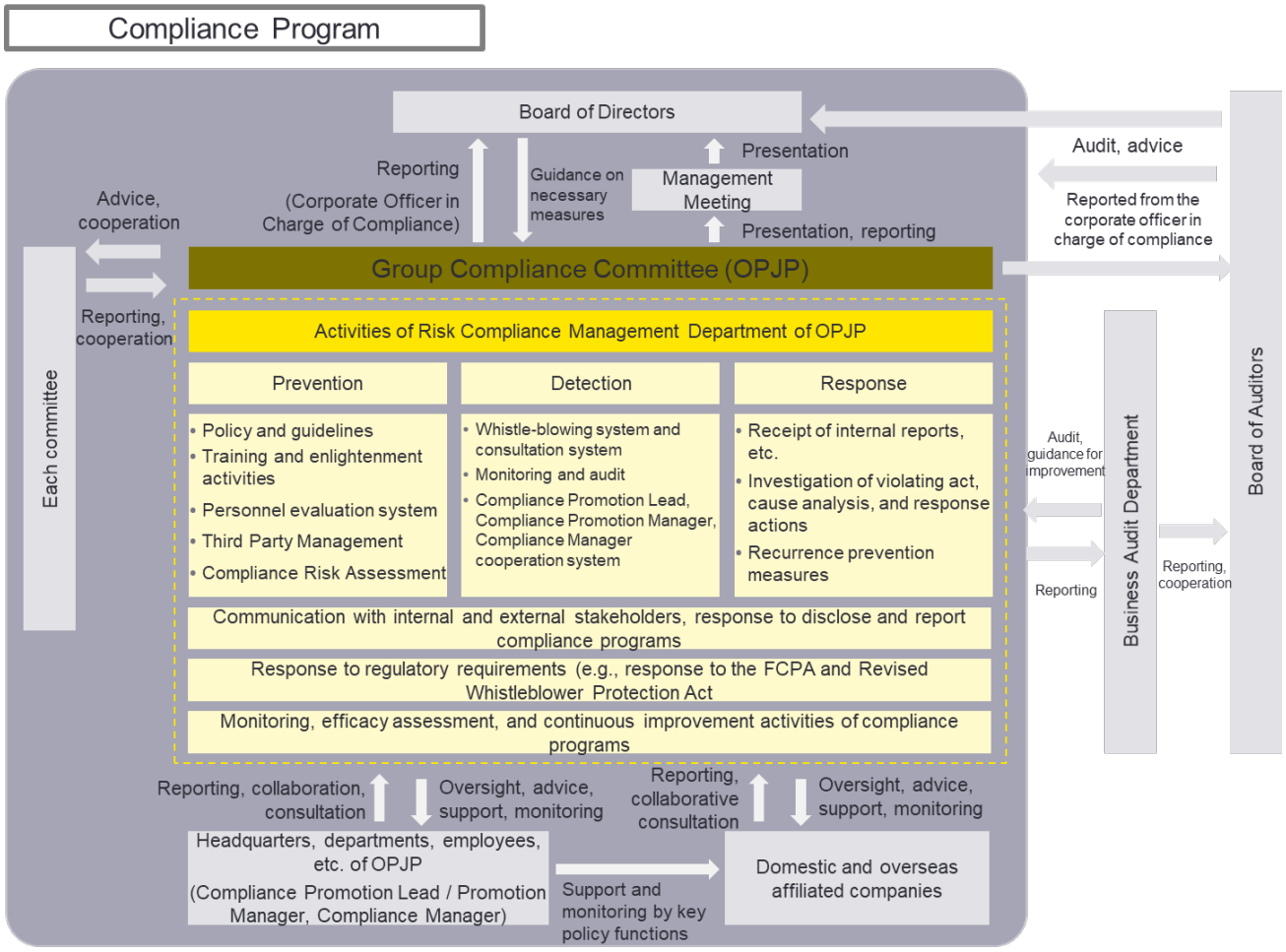
retirees or business partners.

31. Response to International Standards and Overseas Laws and Regulations and Contribution to Local Societies

[1] We will respect not only international rules and related local laws, regulations, etc., but also local cultures and practices in international business activities.

[2] We will also ask domestic and overseas group companies and business partners, etc., to comply with international rules and related local laws, regulations, etc., as well as to respect local cultures and practices while conducting international business activities.

Appendix 2 Conceptual Diagram



Appendix 3 List of Matters for Prior Consultation or Reporting

Prior Consultation		● Planning and implementation of activities related to the Compliance Program ● Enactment, revision or abolition of compliance-related policies at Affiliated Companies designated by the Risk & Compliance Management Department of OPJP ● Appointment or hiring of manager of Compliance Supervisory department, etc. at Affiliated Companies
Reporting	Matters requiring immediate Reporting	● Significant violation or suspected significant violation of laws and regulations applicable to Ono Group or internal rules of Ono Group (cases where actions such as administrative guidance or recommendation from related ministries, agencies, or authorities or initiation of investigation is expected, cases requiring reporting to related ministries, agencies, or authorities, or cases resulting in disciplinary action) ● Initiation of investigation or on-site inspection (dawn raid) by related ministries, agencies, or authorities ● Actions such as administrative guidance, recommendation, and order from related ministries, agencies, or authorities ● Arrest of Employees, etc. of Ono Group by police authorities, etc., initiation of investigation against Employees, etc. of Ono Group ● Filing, ruling, or decision in lawsuits or similar legal proceedings against an Ono Group company or its Employees, etc. ● Fatal accidents occurring in association with clinical trials or attributed to our products ● Personal information accidents (accidents involving leakage, unintended use, etc., of domestic or overseas personal information or personal data handled by Ono Group) ● Major accidents such as fire and explosion or damage to facilities caused by natural disasters, mainly in plants or laboratories, which hinder smooth operation of business ● Other matters requiring external announcement or reporting to supervisory agencies or Tokyo Stock Exchange ● Including cases where the above matters requiring immediate reporting occur at a business partner, consignee or other third party

	Contents subject to quarterly Reporting	*If it is urgent, report it to Risk & Compliance Management Department of OPJP promptly. ● Progress status and contents of activities related to the Compliance Program ● Materials and minutes of each committee and Compliance Committee of Affiliated Companies established within OPJP or decision making meeting equivalent thereto (the relevant committee within OPJP is designated by Corporate Officer in charge of Compliance) ● Information on establishment, revision, and abolition of compliance-related laws and regulations, industry codes, and various rules ● Operational audit observations (matters related to compliance) ● Compliance-related policies of Affiliated Companies that have been enacted, revised or abolished (excluding those consulted in advance)