

Material Issue 16

Thorough Compliance

Management of Priority Issues

Reason for being a priority issue	As a pharmaceutical company involved in pharmaceuticals upon which human lives depend, we must not only comply with laws and regulations but also act in accordance with high ethical standards. In addition, compliance problems are a serious risk that could damage our brand and trust, which are our important non-financial assets, as well as affect the continuation of our business.
Vision over the medium to long term	Establish a compliance risk management system to support global business expansion and prevent compliance violations.
Indicators	Number of significant compliance violations*: 0 * Violations that have a great impact on sales and profits and have a great social impact
Major initiatives	<ul style="list-style-type: none"> Establish overall risk management (ERM) for global response, including compliance Comply with relevant laws and regulations of the pharmaceutical business, promote proper use of pharmaceuticals, prevent corruption and corrupt practices, protect information, etc. Foster a culture of proactive involvement in preventing compliance violations Strengthen governance of compliance risks by the Board of Directors

ONO PHARMACEUTICAL Compliance System

Being aware of our responsibilities as a pharmaceutical company dealing in pharmaceuticals upon which human lives depend, ONO has a Code of Conduct, the ONO PHARMACEUTICAL Code of Conduct, to ensure that it acts in compliance with laws and regulations and that it meets high ethical standards. Under our Corporate Philosophy, we established our Code of Conduct as a basic guideline for corporate activities and the Compliance Program Policy as the behavioral standard for those activities. We also formulated and comply with our Code of Practice, which is based on the Japan Pharmaceutical Manufacturers Association (JPMA) Code of Practice for promotional activities. In practicing our compliance system, we make sure our employees know about ensuring transparency, preventing fraud and corruption, and are constantly aware of domestic and international social conditions.

Compliance System



[Web](https://www.ono-pharma.com/company/mission.html) Corporate Philosophy / ONO PHARMACEUTICAL Code of Conduct

[Web](https://www.ono-pharma.com/company/policies/compliance.html) ONO PHARMACEUTICAL Compliance Program Policy

[Web](https://www.ono-pharma.com/company/policies/cop.html) ONO PHARMACEUTICAL Code of Practice

Compliance Promotion System

To promote compliance, we have appointed the Executive Director of Corporate Strategy & Planning, who is a Senior Executive Officer and a Member of the Board of Directors, as the Corporate Compliance Officer and set up a Compliance Committee. This Committee examines and deliberates on compliance-related issues, plans and promotes relevant training programs. It also cooperates with the internal auditing department checks the status of initiatives at each business location. In addition, the Compliance Committee manages risk in cooperation with the Risk Management Committee. In FY2021, because of the serious compliance violation that occurred in the previous fiscal year, we took measures to prevent recurrence, including the implementation of company-wide training. We also worked to strengthen the Board of Directors' supervisory system by regularly reporting the progress of such measures (e.g., the status training implementation) to the Board of Directors and receiving advice from outside directors. In addition, a Compliance Officer has been appointed in each division to be in charge of strengthening compliance. In addition, a risk manager, who is responsible for overall risk management of the organization, works with compliance managers, who have been newly assigned to all departments to serve as consultation counters for compliance issues in the workplace, to establish an operational system that promptly takes measures to respond to consultation issues raised within the organization. Information on consultation

cases is also shared with the Assessment Office, newly established within the Compliance Division, which provides advice to the compliance managers.

In the Sales and Marketing Division, a specially assigned compliance officer is in charge of overall compliance. The officer regularly participates in compliance promotion meetings within the division and provides advice and suggestions to ensure proper operations and to establish an awareness of preventive measures. We provide guidance to group companies in creating systems and rules to prevent the occurrence of noncompliance, and we urge our suppliers to do the same.

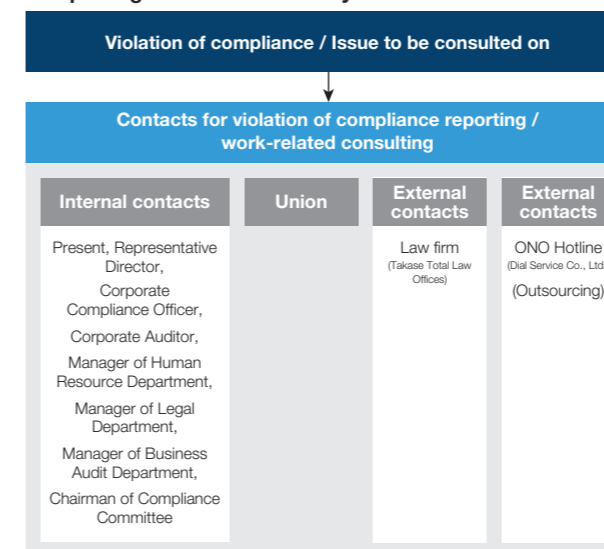
Reporting and Consultation System

We have internal and external contact windows, such as the 24-hour external contact service called the ONO Hotline, which was set up to prevent compliance violations, including harassment, to ensure appropriate work environments, and to take measures promptly to minimize any loss of social credibility in the event of a compliance violation. We also have a system to ensure that informants can directly report to or consult with top management—that is, the Representative Director, the Corporate Compliance Officer, or the Corporate Auditors. We ensure that matters concerning privacy, such as the informant's name and reported content, are kept strictly confidential, and are not disclosed except to those necessary for the survey, and we also support anonymous reporting. In addition, we do not bring detriment to such an informant solely because of the use of the system and they are legally protected. These are clearly stated in the Whistleblower Regulations, which were newly established in light of the revised Whistleblower Protection Act that came into force in FY2022, and are thoroughly communicated to all employees. Furthermore, we are working to make the system available in the entire group so that employees and others can report or consult without hesitation.

Compliance Education

To promote compliance, we recognize that it is important to

Reporting and Consultation System



[Web](https://sustainability.ono-pharma.com/en/themes/81#911) Reporting and Consultation System

continually conduct employee training and awareness-raising activities. We therefore provide compliance training to our officers and all employees every year.

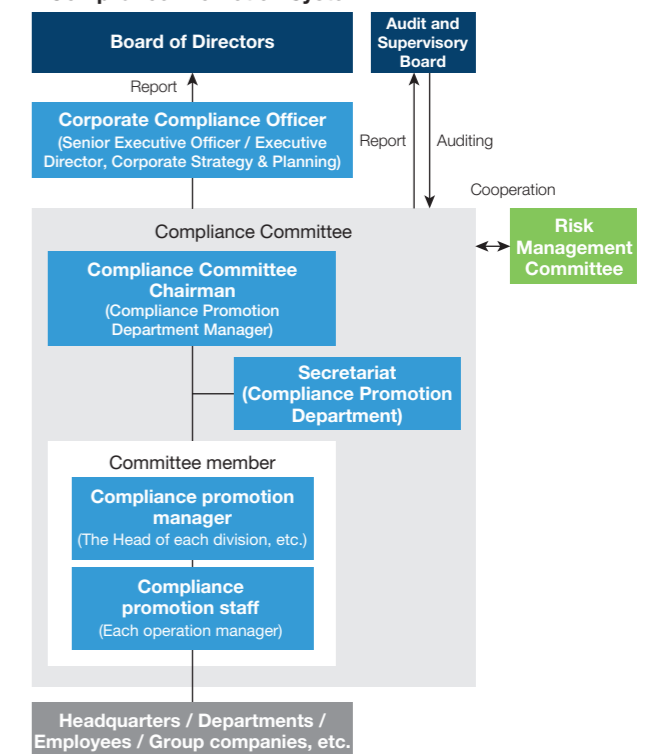
In FY2021, taking a lesson from the serious case of noncompliance that occurred in the previous fiscal year, we conducted training sessions with discussions to thoroughly prevent recurrence, as well as education and training on preventing bribery. We also conduct training on harassment annually, and are strengthening our efforts to create a comfortable work environment.

As for the training related to the Guidelines on Activities to Provide Sales Information, the contents of the training are based on actual compliance issues. We provide not only regular training, but if a problem arises, we also conduct training as soon as possible to prevent recurrence. We also promote risk-based training programs for other compliance themes.

Ethical Considerations

We always give consideration to ethical treatment in various stages of research and development. For research using human-derived samples (blood, tissue, cells, genes, etc.), we have established internal ethical rules based on the basic guidelines issued by the Japanese government. We have also established an advisory body, the Ethics Committee for Medical and Health Research Involving Human Subjects, comprising members from inside and outside the company, to ensure that such research is conducted only after the Committee conducts strict assessment of its ethical and scientific validity. For research using laboratory animals, we have established an Institutional Animal Care and Use Committee. The Committee reviews submitted animal experimentation plans in advance to determine whether they have been prepared based on the principles of the 3Rs* to ensure that animal experiments are

Compliance Promotion System



Value Preservation

carried out appropriately, with respect for the lives of animals and taking into consideration animal welfare. In addition, we conduct self-inspections and assessments of the implementation status of animal experiments. In recognition of these initiatives, we have acquired third-party certification from the Japan Pharmaceutical Information Center.

We ensure that clinical trials, which are essential for verifying the safety and efficacy of pharmaceuticals under development, are carried out in a highly ethical manner, with respect for the human rights and with particular attention to the safety of study subjects. We ascertain the true value of drugs step-by-step by taking all necessary and appropriate procedures that comply with Japan's "Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Pharmaceutical and Medical Device Act)" and other related legislation, as well as the global standards specified based on the spirit of the Declaration of Helsinki. In the past, many drug-induced injury cases occurred due to inadequate monitoring of the safety of pharmaceutical products. We regularly provide education on drug-induced injuries to all employees so that they will never forget patients' pain, the tragedy of the drug-induced suffering, and the grave responsibility of a pharmaceutical company.

* Internationally accepted and established principles for the proper care and keeping of laboratory animals and animal experimentation. The 3 principles are Replacement (use of alternative methods), Reduction (reducing the number of test animals) and Refinement (alleviation of pain).

Web Human Rights

https://www.ono-pharma.com/company/policies/respect_human_rights.html

Web Animal Ethics

https://www.ono-pharma.com/company/policies/ethical_considerations_in_animal_experiments.html

Fair and Transparent Business Activities

In order to conduct fair and transparent business activities, we have e-learning and also a reinforcement month for training in each division. We provide thorough education to all employees about the prevention of fraud and corruption every year.

To contribute to healthcare and people's health around the world through continuous new drug creation and a stable supply of our products, collaborative activities support for patient organizations to help patients overcome disease and pain, and cooperation with research and medical institutions is indispensable. To enhance the fairness and transparency of these cooperative and collaborative activities, it is important to ensure transparent relationships with our partners. We therefore disclose information on the costs of our assistance to medical institutions and patient organizations in accordance with our transparency guidelines, which were developed in line with the relevant guidelines of JPMA.

Regarding tax compliance, we have established a global tax policy, the ONO PHARMACEUTICAL Global Tax Policy. All tax-related work is undertaken in strict accordance with this policy and under the responsibility of the director in charge of compliance, namely the Executive Director of the Corporate Strategy & Planning Division, who is a Senior Executive Officer and Member of the Board of Directors.

Amid globally mounting interest in compliance with laws governing unfair and corrupt practices, we established the ONO PHARMACEUTICAL Global Anti-Bribery and Corruption Policy and the Regulations on Bribery Prevention in 2017 to clearly define and state our company's stance and system in preventing bribery and corruption. We endeavor to ensure strict implementation of the policy and regulations. Furthermore, we support Transparency

International's Business Principles for Countering Bribery, an international anti-bribery standard.

As for research receiving public funds as research funding, we have formulated the Action Guidelines for Publicly Funded Research and the Regulations on Publicly Funded Research, in compliance with the relevant guidelines established by the Japanese government, to ensure further appropriate implementation and management of research projects.

Web Engagement to Achieve Transparency in Relationships with Medical Institutions, etc. (only in Japanese)

<https://sustainability.ono.co.jp/ja/themes/120#1021>

Web Engagement to Achieve Transparency in Relationships with Patient Groups (only in Japanese)

<https://sustainability.ono.co.jp/ja/themes/120#1022>

Web Operation and Management System of Public Research Funds

https://www.ono-pharma.com/company/policies/public_research.html

Web ONO PHARMACEUTICAL Global Tax Policy

https://www.ono-pharma.com/company/policies/tax_policy_jp.html

Web Tax Reporting by Country

<https://s3-ap-northeast-1.amazonaws.com/sustainability-cms-ono2020-en-csr-s3/data/pdf/tax/Tax%20Reporting%20by%20Country%20for%20the%20Fiscal%20Year%20Ended%20March%2031,%202021.pdf>

Web ONO PHARMACEUTICAL Global Anti-Bribery and Corruption Policy

https://www.ono-pharma.com/company/policies/bribery_prevention_globalpolicy.html

Pursuit of Fair Promotion Activities

We define "promotions" as "Providing and transmitting drug information to healthcare professionals and promoting the proper use and spread of ethical drugs based on such information." All employees involved in promotions carry out fair promotion activities, while always examining whether they are acting in accordance with the spirit of the ONO PHARMACEUTICAL Code of Practice, which conforms with the JPMA Code of Practice, regardless of whether there are specific provisions or descriptions in the Code. Furthermore, based on the Company's Code, we not only comply with the Guidelines on Activities to Provide Sales Information on Prescription Drugs issued by the Ministry of Health, Labour and Welfare of Japan, and the Promotion Code for Prescription Drugs established by JPMA, but also respect the IFPMA (International Federation of Pharmaceutical Manufacturers & Associations) Code of Practice.

Web Responsible Promotion Activities

<https://sustainability.ono-pharma.com/en/themes/83>