

Feature 03

Response to risks based on ERM

Business activities involve environmental issues, natural disasters, violation of laws, and various other risks in addition to the risks unique to pharmaceutical companies. ONO introduced Enterprise Risk Management (ERM) in FY2019 so that we can make optimal decisions and provide responses from a company-wide perspective. We are improving our cross-sectional ability to manage risks by identifying them and establishing countermeasures primarily through the Risk Management Office, which was established in April 2019.

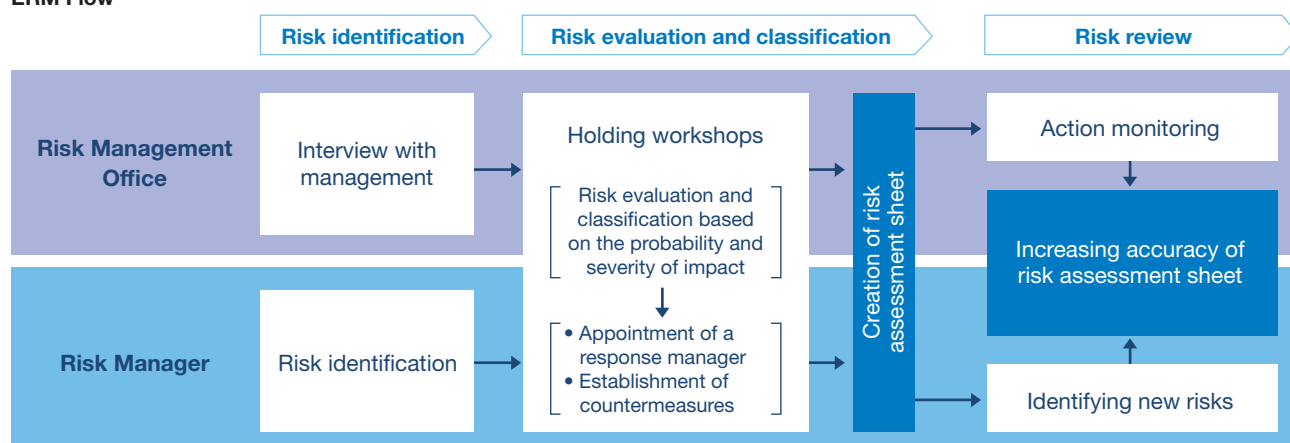
Management and persons in charge identify risks and the risks are evaluated and classified by workshop

In the first step to promote ERM, we identified risks related to our company. First, the Risk Management Office interviewed management and identified risks that the management considered to be important. Next, the Risk Management Office appointed several risk managers (persons in charge with the initiative to conduct risk management activities in each division) from each division and evaluated and classified risks in the form of workshops. Risks that were considered by management and risks collected by each risk manager were discussed along with possible scenarios in the workshop. They evaluated the probability of said risks across 7 levels and the severity of impact when a risk occurs across 5 levels, arrived at a risk index, and classified each risk as Significant, High, Medium, and Low. The response manager and countermeasures for each risk were also determined. The Risk Management Office adjusted duplications and deviations in standards and compiled said risks and countermeasures in a Risk Assessment Sheet after obtaining confirmation by each division.

Establishing the ERM system and periodic monitoring of response conditions

The response manager is designated to identify risks and assumes responsibilities for countermeasures. In particular, concerning risks that should be handled intensively, we established a system to select them as Serious Risks at the Management Meeting, allocate resources on a preferential basis, and take actions and conduct monitoring company-wide. Furthermore, concerning complex risks requiring urgent and company-wide actions, such as massive natural disasters and novel coronavirus infectious disease (COVID-19), possible risk scenarios will be developed, a system will be arranged by identifying an overall picture, and then issues will be resolved. The Risk Management Office takes the initiative and monitors actions against these serious risks and actions taken by each department. In addition, the Risk Management Office periodically adds new risks and reviews the risk index in association with environmental changes in cooperation with risk managers. Through these activities, ONO continues to increase the accuracy of the risk assessment sheet and strives to reduce risks.

ERM Flow



Major Risks and Countermeasures (extract)

There are 18 major risks that ONO indicated in the Securities Report in FY2019. Among others, the following six items were judged to have particularly high impact and risk. We also identified risks unique to ONO and new risks in addition to the aforementioned risks.

Risk factors	Risk outline	Countermeasures
Development of new products	<ul style="list-style-type: none"> Long-term and significant investment in research and development did not result in the release of inventive new drugs and development was abandoned. 	<ul style="list-style-type: none"> Strengthening a system to engage in our drug discovery by focusing on research fields. Adopting the world's most advanced technologies and knowledge and promoting open innovation to increase the speed of new drug development and the probability of success.
Changes in market environment	<ul style="list-style-type: none"> Decreases in product competitiveness due to sales conditions of competing products and generic products. 	<ul style="list-style-type: none"> Maximize product value by conducting proactive research and development activities, prompt cooperation between departments throughout the company, and strengthening functions to foster human resources. Review of strategy that can always ensure competitive superiority for each product stage and protecting resources to achieve it.
Compliance	<ul style="list-style-type: none"> Decreases in trust if our Group and contractors cause a critical violation of laws. Restriction of business activities due to amendment of laws and regulations, etc. and investment in countermeasures. 	<ul style="list-style-type: none"> Development and practice of the compliance system based on the ONO PHARMACEUTICAL Code of Conduct. Establishment of the compliance promotion system. Thorough compliance with laws and regulations related to business activities.
Product quality control	<ul style="list-style-type: none"> In the event of serious quality problems or concern over the safety and security of products based on new scientific knowledge, the brand value of the product may decrease and the trust in entire our group may be damaged. 	<ul style="list-style-type: none"> Establishment and continued improvement of the quality control system based on the original quality control manual. Development of the system to promptly respond to cases that concern product quality, efficacy, and safety.
Acquiring and fostering human resources	<ul style="list-style-type: none"> Stagnation of business activities if diverse and excellent human resources cannot be acquired and fostered in the medium- and long-term. 	<ul style="list-style-type: none"> Development of a support system and work environment where multiple workstyles are allowed. Implementation of the training system based on individual growth and capability. Promotion of women's participation and advancement, promotion of the activities of people with disabilities, and promotion of employing mid-career individuals.
Natural disasters and accidents in association with large-scale earthquakes and climate change	<ul style="list-style-type: none"> Stagnation of business activities due to natural disaster in association with large-scale earthquakes and climate change, explosions and fire accidents at production plants, information and control system troubles, problems at raw materials suppliers, functional failure of society's infrastructure such as electricity, water, etc., environmental pollution by hazardous substances, terrorism, political turmoil, riot, etc. 	<ul style="list-style-type: none"> Establishment of disaster measures and business continuity plan (BCP) for production plants and major business bases. Actions for climate change risks based on the proposal of TCFD. Strengthening ability to handle emergency situations by development of the 2 bases system, introduction of the Safety Confirmation System, and conducting periodic disaster-drills.

▶ Part of the major risks identified in the Securities Report are extracted and indicated in the above table. For more details, please see the following Securities Report (only in Japanese) and CSR website.

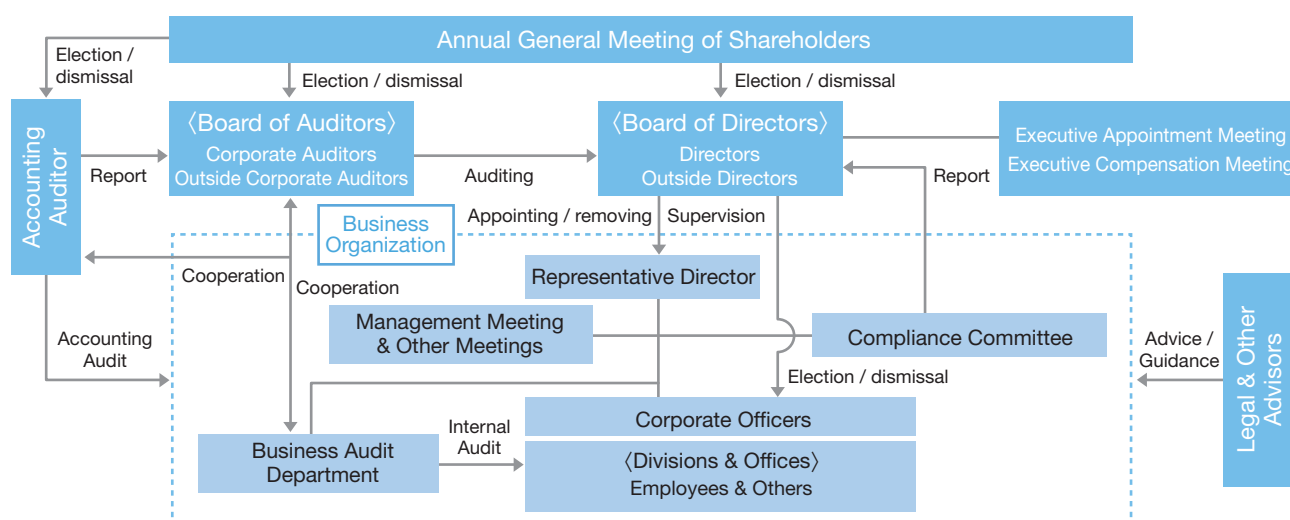
https://www.ono.co.jp/jpnw/ir/pdf/y_houkoku/ns_ver4_200619.pdf

Corporate Governance

Corporate Governance Structure

As part of our endeavors to strengthen corporate governance, ONO has adopted an organizational framework with a Corporate Auditor (or Board of Corporate Auditors) whose task is to focus on enhancing the functions of the Board of Directors and the Board of Corporate Auditors. ONO has established the Executive Appointment Meeting and the Executive Compensation Meeting, both of which are comprised mainly of Outside Directors in order to ensure independence and objectivity with regard to the appointment and remuneration of the Executive Members.

Regarding business execution, we have adopted a corporate officer system to improve management efficiency and speed up decision-making. On the other hand, depending on the importance and contents of the management issues, important matters related to business execution are deliberated and determined by the Management Meeting and other meetings chaired by the responsible Members of the Board of Directors or Corporate Officers. Thus we strive to achieve optimal business operations by ensuring effective working of mutually supervisory functions.



Board of Directors

As for board members, we select the candidates taking into consideration the balance and diversity of their knowledge, experience, and proficiency, so that the Board of Directors as a whole can make technical and comprehensive management decisions. The term of office for each director is limited to one year. This serves to clarify their responsibility, and it allows the board to respond flexibly to changes in the management environment.

The board system is determined in a way that is optimally suited to enforcing management transparency, enhancing corporate governance and making decisions promptly and accurately. Currently, the board consists of eight members, including three outside directors. The board holds meetings every month in principle to deliberate and make decisions on important management issues and to assess how each board member is conducting his or her duties. In addition, the board places great weight on the opinions of the auditors, and also incorporates the perspectives of legal, financial and accounting experts, as well as gender perspectives, into its deliberations.

Board of Auditors

To maintain a strong auditing function, the Board of Auditors comprises two independent outside auditors along with two full-time auditors who have expert knowledge on our business operations and who are highly skilled in collecting auditing information. These full-time and outside auditors work together to achieve high auditing efficiency.

The Board of Auditors holds meetings regularly. Working with the internal auditing department (Business Audit Department) to enforce auditing efficiency, the Board of Corporate Auditors

endeavors to improve its functions of the management oversight by enhancing the effectiveness of audits in cooperation with the accounting auditor.

Executive Appointment Meeting

The Executive Appointment Meeting comprises the company president who serves as the chairperson, one internal director and three external directors. It is charged with deliberating our company's approach to corporate governance, including ensuring transparency and objectivity in the nomination of members of senior management, as well as candidate board members and auditors. Its duties also include formulation of plans for succession for the chief executive officer (president/CEO) and other senior management. Executive appointments, requiring consultation by the Board of Directors, are decided after being placed on its agenda upon deliberative review by the Executive Appointment Meeting.

Executive Compensation Meeting

The Executive Compensation Meeting comprises the company president who serves as the chairperson and three external directors. Its duties include ensuring transparency and objectivity in determining the amount and calculation of remuneration for each individual board member. It also deliberates the appropriateness of the remuneration system for board members and our ongoing approach to maintaining the system. Executive remuneration, etc., requiring consultation by the Board of Directors, is decided after being placed on its agenda upon deliberative review by the Executive Compensation Meeting.

Evaluation of the Effectiveness of the Board of Directors

ONO conducts self-evaluations on the composition, operation and other matters of the Board of Directors once a year with the aim of improving the effectiveness of the Board of Directors as a whole.

Results of analysis and evaluation of the effectiveness of the Board of Directors as a whole conducted in FY2019 are summarized as follows:

(1) Method of evaluation

ONO conducted a questionnaire survey of all Members of the Board of Directors and all Audit & Supervisory Board Members (excluding Outside Corporate Auditors who resigned due to illness) requiring respondents to provide their names in the answer sheets, as well as one-on-one interviews with them, after explaining the purpose of the evaluation of the effectiveness at a meeting of the Board of Directors. Based on the answers and opinions gained from the survey and interviews, the Board of Directors conducted analysis and self-assessments of its effectiveness and discussed challenges to tackle as well.

Contents of the questionnaire and interviews

- Size and composition of the Board of Directors
- Operation of the Board of Directors
- Roles and responsibilities of the Board of Directors

(2) Summary of results of analysis and self-evaluation of the effectiveness

- The Board of Directors makes important management decisions in an expeditious and appropriate manner, and the system that allows appropriate supervision of business execution has been ensured.
- Measures have been taken on an ongoing basis to improve the operation of the Board of Directors, including a review of matters for deliberation at the Board of Directors in light of the management environment and the situation of the Company.
- Members of the Board of Directors and Audit & Supervisory Board Members, including Outside Directors and Outside Audit & Supervisory Board Members, are freely expressing their opinions from their own perspectives, based on the common understanding of the corporate philosophy and the management issues of the Company.

Based on the results above, ONO concluded that the effectiveness of the Board of Directors of the Company has been ensured.

(3) Initiatives towards the improvement of the effectiveness

Amid the drastically changing environment surrounding the Company, the Board of Directors of the Company will further improve its effectiveness by enhancing discussions on the direction of management from a medium- and long-term perspective.

Executive Remuneration

〈Policy on Determining Remuneration〉

The remuneration of Members of the Board Directors, excluding Outside Directors, consists of fixed remuneration, bonuses, and stock-based remuneration-type stock options, while the remuneration of Outside Directors and Audit & Supervisory Board Members consist of fixed remuneration only.

Fixed part of the remuneration of Members of the Board of Directors, excluding Outside Directors, is set at an appropriate level by taking into account the business scale of the Company, duties and weight of responsibility of individual Members of the Board of Directors, consistency with the treatment of employees and other factors, while also referring to the executive remuneration database of a major consulting firm. The amount of bonus to be paid and the number of stock-based remuneration-type stock options to be granted are determined by taking into account the management indicators, such as sales and operating profit that reflect financial performance, as well as the degree of achievement of qualitative activity indicators, including contributions to an increase in corporate value over the long term.

Outside Directors and Audit & Supervisory Board Members only receive fixed remuneration in light of their responsibilities and independence from business execution. The level of remuneration of Outside Directors/Outside Audit & Supervisory Board Members is set by also referring to the executive remuneration database of a major consulting firm so that the Company can invite suitable persons with ample experience and extensive knowledge from a wide-ranging group of people.

〈Procedures for Determining Remuneration〉

The remuneration of individual Members of the Board of Directors is discussed and determined by the Board of Directors based on the above policy and within the amounts approved at the Ordinary General Shareholders' Meeting after deliberation by the Executive Compensation Meeting.

The remuneration of Audit & Supervisory Board Members is determined within the maximum amount approved at the Ordinary General Shareholders' Meeting through discussion among Audit & Supervisory Board Members.

Executive Remuneration for FY2019 (Results)

Executive category	Number of executives to receive remuneration	Fixed remuneration	Bonuses	Stock options	Total amount of remuneration
Members of the Board of Directors, excluding Outside Directors	5	¥221 million	¥81 million	¥27 million	¥328 million
Outside Directors	3	¥40 million	—	—	¥40 million
Audit & Supervisory Board Members, excluding Outside Audit & Supervisory Board Members	2	¥56 million	—	—	¥56 million
Outside Audit & Supervisory Board Members	2	¥22 million	—	—	¥22 million
Total	12	¥338 million	¥81 million	¥27 million	¥446 million

Outside Directors / Outside Auditors

The outside directors attended all meetings of the Board of Directors held in FY2019. From an independent and objective standpoint, they oversee our business operations and take part in our decision-making process. They are involved in the process of making important decisions such as nomination of officers and executive compensation, help to ensure the transparency and objectivity and enhance the functions of the board by serving as members of the Executive Appointment Meeting and the Executive Compensation Meeting. In FY2019 the Executive Appointment Meeting was held 3 times and the Executive Compensation Meeting was held twice, and all meetings were attended by the outside director.

The outside auditors (excluding auditors who resigned due to illness) attended all meetings of the Board of Directors and the Board of Auditors held in FY2019. As experts in law and corporate accounting, the outside auditors carry out the audits from an independent and objective standpoint to ensure that our management remains sound and strong.

Outside officers provide useful advice and suggestions for our business management based on their abundant experience and profound knowledge.

There is no special interest relationship between these outside officers and ONO such as personal relationships, capital relationships, and business relationships, based on which we

believe there is no risk of conflict of interest with general shareholders.

Training Policy for Directors and Audit & Supervisory Board Members

ONO appoints candidates for Member of the Board of Directors and Audit & Supervisory Board Member, including those for Outside Directors and for Outside Audit & Supervisory Board Member, from those who are considered capable of fulfilling their expected roles and responsibilities. The Members of the Board of Directors and Audit & Supervisory Board Members newly appointed from within our company then attend outside seminars, in order to deepen their understanding of the roles and responsibilities of Members of the Board of Directors and Audit & Supervisory Board Members. Conversely, for Outside Directors and for Outside Audit & Supervisory Board Members, we provide training, with consideration of their background, to deepen their understanding of the business of the Company and industry trends. ONO also offers and arranges opportunities for training necessary for individual Members of the Board of Directors and Audit & Supervisory Board Members after their appointment, and bears the cost of such training.

Expected Roles of Outside Directors and Outside Auditors

	Name	Expected roles	Attendance at meetings (Results in the fiscal year that ended in March 2020)
Outside Director	Jun Kurihara	With broad knowledge and abundant experience gained from research inside and outside Japan and as one of the leading researchers in fields related to politics, the economy, and society, Mr. Kurihara has fulfilled important roles as an outside director by providing appropriate supervision to our company management from an independent standpoint as well as useful advice and suggestions. We expect that he will contribute to maintaining and improving sound management and appropriate operation by being involved in the management of our company as an outside director.	Meeting of Board of Directors: 13 times / 13 times Executive Appointment Meeting: 3 times / 3 times Executive Compensation Meeting: 2 times / 2 times
	Masao Nomura	Mr. Nomura has abundant experience and advanced knowledge as he has served as a management executive over the years and he has fulfilled important roles as an outside director by providing appropriate supervision of our company management from an independent standpoint as well as useful advice and suggestions. We expect that Mr. Nomura will continue to be involved in our company management as an outside director and thereby contribute to increasing our company value.	Meeting of Board of Directors: 13 times / 13 times Executive Appointment Meeting: 3 times / 3 times Executive Compensation Meeting: 2 times / 2 times
	Akiko Okuno	Ms. Okuno has extensive academic knowledge as a university professor specializing in business administration. We expect her to provide us with valuable advice and suggestions based on her knowledge of specialized fields, such as women's labor and personnel evaluation systems. We believe that she will contribute to the enhancement of corporate values by becoming involved in our management as an outside director in the future.	(Appointed June 2020)
Outside Auditor	Yasuo Hishiyama	With abundant experience and advanced knowledge of corporate legal affairs as an attorney-at-law, Mr. Hishiyama has fulfilled important roles as an outside auditor by providing appropriate supervision of the operations of our company directors from an expert and independent standpoint as well as findings and suggestions if needed. We expect that he will contribute to maintaining and improving sound management and appropriate operation by being involved in the management of our company as an outside auditor.	Meeting of Board of Directors: 13 times / 13 times Meeting of Board of Auditors: 14 times / 14 times
	Akiko Tanabe	With abundant experience and considerable knowledge of accounting as a certified public accountant, we expect Ms. Tanabe to provide us with supervision of the operations of our company directors from an expert and independent standpoint as well as findings and suggestions as required. We expect that she will contribute to maintaining and improving sound management and appropriate operation by being involved in the management of our company as an outside auditor.	(Appointed June 2020)

Internal Control System

ONO has laid out our operational system in compliance with the internal control system set out at the board of directors meeting. We also strive to ensure compliance and detect internal control problems at an early stage through auditing by the Internal Auditing Department (Business Audit Department) and we thereby maintain and improve the appropriateness of organizational management. Furthermore, we have established compliance notification and consultation windows in and outside the company to increase the self-cleansing function of the organization and to reduce reputation risks due to notification outside the company. The development and operation status of the internal control system is reported periodically to the board of directors meeting with the aim of constantly improving organizational operation.

Concerning antisocial forces or organizations that may threaten social order or security, we communicate our firm stance to fight against them throughout our organization.

Operational Management Structure

For the improved efficiency and accuracy of our decision making and business operations, we hold Management Meetings and other meetings attended by the president, board members, corporate officers in charge of each division, and managers of relevant departments. At these meetings, we take a multifaceted approach to addressing important management issues, including those that are to be deliberated on at board meetings. We also aim to maintain and improve management efficiency and make quicker decisions by introducing a corporate officer system and promoting transfer of authority. Auditors are obliged to attend Management Meetings and inspect their minutes, as these meetings are also subject to auditing.

Corporate Governance Code

ONO has been following all principles indicated in the Corporate Governance Code stipulated by the Tokyo Stock Exchange. In consideration of the intent of the Corporate Governance Code, we are committed to improving the efficiency, soundness and transparency, etc. of the management, and promoting our system more suitable for our business operations, through the evaluation on the effectiveness of the annual meeting of the Board of Directors.

▶ For more details on our company's corporate governance, please refer to the following Corporate Governance Report.

https://www.ono.co.jp/eng/investor/pdf/c_governanc/c_governanc_20200625.pdf

Information Disclosure

As specified in our Codes of Conduct, we strive to establish transparent corporate management and recognize the importance of taking various opportunities to disclose information on our business activities in a timely and appropriate manner. We actively conduct investor relations (IR) activities based on a policy of pursuing accuracy, promptness, fairness, and impartiality.

We disclose financial results and other timely disclosure information on our website and at the same time through TDnet, the timely disclosure network of the Tokyo Stock Exchange. Information that is not subject to the timely disclosure rules is also disclosed swiftly through our website and by other means. For securities analysts and institutional investors, we actively hold individual meetings and phone conferences in addition to a financial results briefing or a conference call at the time of each quarterly statement, having held 220 meetings in total in FY 2019. We also participate diligently in investor conferences sponsored by security firms and the like in order to facilitate individual investors' understanding of our business activities and management strategy.

Our website contains an IR library that provides useful current and past data, including development progress updates, as well as financial highlights for the last five years. Also, we endeavor to convey our corporate information to a wider range of people in an easy-to-understand manner by issuing business reports (shareholder newsletters) and integrated reports. We will disclose the information more accurately and promptly.

Management (as of June 18, 2020)



Gyo Sagara

President, Representative Director, and Chief Executive Officer

Number of the Company's shares held 54,000	
April 1983	Joined the Company
April 2006	Executive Director, General Administration and Senior Director, Corporate Management
June 2006	Member of the Board of Directors
April 2007	Executive Director, Corporate Management
November 2007	Executive Director, Sales and Marketing
December 2007	Managing Member of the Board of Directors
February 2008	Member of the Board of Directors, Vice President
April 2008	Executive Director, Corporate Management
September 2008	President & CEO (to date)



Hiroshi Awata

Member of the Board of Directors, Vice President
Executive Officer
Tokyo Branch Head

Number of the Company's shares held 32,900	
April 1983	Joined the Company
May 2008	Executive Director, Clinical Development and Senior Director, Clinical Development Planning
June 2008	Member of the Board of Directors
June 2009	Managing Member of the Board of Directors
June 2010	Senior Managing Member of the Board of Directors
June 2011	Member of the Board of Directors, Senior Executive Officer
October 2011	Executive Director, Clinical Development and Senior Director, Clinical Development Management
May 2012	Executive Director, Clinical Development
June 2012	Member of the Board of Directors, Vice President Executive Officer (to date)
October 2014	Executive Director, Clinical Development and Senior Director, Clinical Development Planning
April 2015	Executive Director, Clinical Development
October 2018	Tokyo Branch Head (to date)



Isao Ono

Member of the Board of Directors, Executive Officer
Director, Corporate Research

Number of the Company's shares held 1,510,275	
April 1981	Joined the Company
February 1986	Member of the Board of Directors
May 1990	Deputy Executive Director, Production
June 1992	Senior Director, Human Resources Development and Assistant Director of Tokyo Branch Office
August 1995	Director, CI
September 2005	Director, Environmental Management
June 2011	Member of the Board of Directors, Corporate Officer
April 2014	Director, Corporate Research (to date)
June 2015	Member of the Board of Directors, Executive Officer (to date)



Toshihiro Tsujinaka

Member of the Board of Directors, Executive Officer
Executive Director, Corporate Strategy & Planning and Senior Director, Business Design

Number of the Company's shares held 8,300	
April 1988	Joined the Company
June 2004	Director, Koshinetsu Branch Sales Division
July 2006	Director, Tokyo Branch 2 Sales Division
November 2007	Senior Director, Sales Operations
August 2008	Senior Director, Marketing Strategy Planning
April 2009	Senior Director, Sales Operations
October 2012	Director, Sendai Branch Sales Division
October 2013	Director, Nagoya Branch Sales Division
October 2015	Senior Director, Oncology Planning & Promotion
April 2016	Division Director, Oncology Business Division
June 2016	Corporate Officer
October 2018	Executive Director, Corporate Strategy & Planning
June 2019	Executive Officer
October 2018	Executive Director, Corporate Strategy & Planning and Senior Director, Business Design (to date)
June 2020	Member of the Board of Directors, Executive Officer (to date)



Toichi Takino

Member of the Board of Directors, Executive Officer
Executive Director, Discovery & Research

Number of the Company's shares held 11,000	
April 1995	Joined the Company
April 2006	Senior Director, International Business
April 2008	Senior Director, Business Development
May 2008	Senior Director, Global Business Development & Licensing
July 2009	Vice President, ONO PHARMA USA, INC.
June 2011	Corporate Officer
April 2012	Executive Director, Corporate Development & Strategy
October 2018	Executive Director, Discovery and Research Division
April 2019	Executive Director, Discovery & Research (to date)
June 2019	Executive Officer
June 2020	Member of the Board of Directors, Executive Officer (to date)



Jun Kurihara

Member of the Board of Directors, Outside Director

Number of the Company's shares held 0	
April 1983	Joined Mitsubishi Research Institute, Inc.
April 1995	Joined FUJITSU RESEARCH INSTITUTE
April 2003	Senior Fellow, Harvard University, John F. Kennedy School of Government
April 2006	Visiting Professor, School of Policy Studies, Kwansei Gakuin University (to date)
April 2007	Liaison Officer, Research Institute of Economy, Trade and Industry
April 2009	Research Director, The Canon Institute for Global Studies (to date)
June 2013	Member of the Board of Directors, Outside Director (to date)

[Status or important concurrent holding of positions]
Research Director, The Canon Institute for Global Studies
Visiting Professor, School of Policy Studies, Kwansei Gakuin University



Masao Nomura

Member of the Board of Directors, Outside Director

Number of the Company's shares held 5,000

March 1972	Joined Iwatani Corporation
June 2007	Director, Executive Officer, Iwatani Corporation
April 2009	Executive Director, Executive Officer, Iwatani Corporation
April 2010	Senior Executive Director, Executive Officer, Iwatani Corporation
June 2012	President, Representative Director, Executive Officer, Iwatani Corporation
April 2017	Director, Senior Adviser to the Board, Executive Officer, Iwatani Corporation
June 2017	Senior Adviser to the Board, Iwatani Corporation (to date)
June 2018	Member of the Board of Directors, Outside Director (to date)
June 2019	Outside Director, Keihanshin Building Co., Ltd. (to date)

[Status or important concurrent holding of positions]

Senior Adviser to the Board, Iwatani Corporation
Outside Director, Keihanshin Building Co., Ltd.



Akiko Okuno

Member of the Board of Directors, Outside Director

Number of the Company's shares held 0

April 2002	Associate Professor, Faculty of Economics, Osaka University of Economics and Law
April 2004	Associate Professor, Faculty of Business Administration, Tezukayama University
April 2010	Professor, Faculty of Business Administration, Tezukayama University
April 2012	Professor, Faculty of Business Administration, KONAN UNIVERSITY (to date)
June 2020	Member of the Board of Directors, Outside Director (to date)

[Status or important concurrent holding of positions]

Professor, Faculty of Business Administration, KONAN UNIVERSITY



Katsuyoshi Nishimura

Audit & Supervisory Board Member

Number of the Company's shares held 10,900

April 1977	Joined the Company
April 2003	Senior Director, Research Management and General Affairs
October 2005	Deputy Executive Director, Discovery & Research and Senior Director, Research Management and General Affairs
April 2006	Deputy Executive Director, Sales and Marketing and Senior Director, Sales Operations
June 2007	Senior Director, Sales Operations
November 2007	Director, Business Audit Department
June 2010	Senior Director, Research Management and General Affairs
June 2011	Full-time Audit & Supervisory Board Member (to date)



Shinji Fujiyoshi

Audit & Supervisory Board Member

Number of the Company's shares held 21,900

April 1980	Joined the Company
May 2006	Director, Tokyo Metropolitan Marketing and Tokyo Branch Office I
February 2008	Director, Marketing Headquarters
June 2008	Director
November 2008	Director, Tokyo Branch Office I
January 2009	Director, Fukuoka Branch Office
March 2010	Director, Marketing Headquarters
June 2010	Managing Director
June 2011	Director and Executive Officer
April 2015	Management, Marketing Headquarters
June 2015	Full-time Audit & Supervisory Board Member (to date)



Yasuo Hishiyama

Outside Audit & Supervisory Board Member

Number of the Company's shares held 0

April 1999	Appointed as a judge (served at Sendai District Court, Saitama District Court and Osaka Family Court)
April 2006	Registered as an attorney at law (Dai-ichi Tokyo Bar Association)
April 2006	Joined TANABE & PARTNERS (to date)
January 2010	Member or appraisal committee (Land Lease Non-Contentious Cases) at Tokyo District Court (to date)
June 2016	Outside Audit & Supervisory Board Member (to date)

[Status or important concurrent holding of positions]

Partner Attorney at Law, TANABE & PARTNERS
Member or appraisal committee (Land Lease Non-Contentious Cases) at Tokyo District Court



Akiko Tanabe

Outside Audit & Supervisory Board Member

Number of the Company's shares held 0

October 1993	Joined Century Audit Corporation (Present: Ernst & Young ShinNihon LLC)
May 1997	Registered as Certified Public Accountant
January 2012	Established Akiko Tanabe CPA office (to date)
June 2015	Outside Director, OIE SANGYO CO., LTD. (to date)
July 2019	Partner of Midosuji Audit Corporation (to date)
April 2020	Provisional Outside Audit & Supervisory Board Member
June 2020	Outside Audit & Supervisory Board Member (to date)

[Status or important concurrent holding of positions]

Representative, Akiko Tanabe CPA office
Outside Director, OIE SANGYO CO., LTD.
Partner of Midosuji Audit Corporation

Messages from Outside Directors (Independent Executives)



(From left to right) Jun Kurihara, Akiko Okuno, Masao Nomura

I will encourage the further growth of ONO through the use of cutting-edge technologies.

Jun Kurihara

Currently the world is terrified of the novel coronavirus. It is a challenging period where contributions of healthcare personnel are being tested and it is an opportunity to reconsider our significance. For these reasons, and with the wish that ONO becomes a company with the potential to become well renowned with high growth, I constantly observe governance from a perspective of stakeholders, including shareholders, and strive to give constructive advice, sometimes with a strict eye. While flows of people, objects, and money are being disrupted under the current crisis, information is flowing around the world with the virus. In particular, advanced technology information related to medical care is being shared and accumulated widely without interruption among first-class management executives and researchers to overcome this crisis. These advanced technologies have a significant

impact on the future of companies. In particular, digital transformation (DX) using information and communication technology (ICT), including artificial intelligence (AI), will activate internal resources as well as connect external resources seamlessly and increase company efficiency. Striving to exchange opinions with first-class researchers concerning AI and DX, I would like to cooperate with ONO's excellent employees and promote DX so that ONO can step out into the world more than ever.

As the saying goes, "the best advice is the hardest to take," one of the duties of an Outside Director is to state constructive advice with the belief that it is "good" for the company even if it is uncomfortable. With my modest experience, I will address further increasing the quality of governance along with other Outside Directors.

I believe that the practice of corporate philosophy will result in an increase in corporate value.

Masao Nomura

Two years have elapsed since I assumed the role of Outside Director of ONO as an independent executive in June 2018. In this fiscal year, I attended all meetings of the Board of Directors during the term and I participated in management with an outside perspective.

Strengthening corporate governance has become more and more important to achieve sustainable growth for the company, expand corporate value, and steadily fulfill our corporate social responsibility. ONO's Board of Directors makes fair and highly transparent management judgments through vigorous question and answer session and opinion sharing and it is in this way that top management members sincerely and proactively address the enhancement of governance.

Global expansion of the novel coronavirus infection has imposed a major issue on human beings: overcoming a new virus. At the same time, it has had a great impact on the global supply chain and increased uncertainty about the future economy.

Under these circumstances, I believe the role of ONO is very important where ONO aims to become a research and development-type global pharmaceutical company with the lofty corporate philosophy: "Dedicated to Man's Fight against Disease and Pain." It is important to continue trying to implement steady investment related to future research and development as well as human resource training and other business plans based on medium- and long-term strategies. I would like to participate in management with a belief that addressing all disease and pain and resolving them one by one will result in increasing our corporate value.

I will make the best use of my experience as a business manager, proactively contribute to transparent and fair business management that is trusted by and satisfies customers, society, employees, shareholders, investors, and all other stakeholders, and thereby support a variety of activities to increase our social significance.

I will also strive to create a foundation to support company development, such as the promotion of women's activities.

Akiko Okuno

Currently, companies are required to act as members of society in addition to pursuing profits. As I have assumed the role of Outside Director of ONO, I feel great responsibility to get involved in the management of decision making as an outside eye in the company. I also have a strong awareness of the significance of my role as a female director. The percentage of female employees of ONO who have taken childcare leave was 100% in FY2019. That of male employees of ONO was 14%. These percentages are significantly higher than the average. ONO has obtained Kurumin Certification* as a company supporting childcare four times since 2018 and in 2019, it obtained Platinum Kurumin Certification, which is a high standard of Kurumin Certification. According to these results, ONO's support in enabling employees' work-life balance has been positive. However, support for work-life balance and the promotion of activities that require

assuming important roles in the organization are different. Japanese society has shifted from support for work-life balance to the promotion of the active participation of women. In this regard, ONO may have room to reform and this is where I can make a contribution.

Speaking of diversity, in many cases, the emphasis is on women in Japan; however, there are multiple axes of diversity, such as nationality, culture, existence of disability, LGBT, and more. Furthermore, companies are required to engage in activities related to environmental measures, CSR, and employee health. These activities will not directly result in an increase in profits. However, they will become a foundation for supporting the company indirectly or in the long term through the employment, use, and training of excellent human resources. I would like to contribute to the further development of ONO, a company with a more than 300-year history.

*Kurumin Certification: A certification by the Minister of Health, Labour and Welfare for childcare support company.

Risk Management

We work to identify potential major risks to prevent them from occurring, and we have a structure in place to ensure that appropriate actions are taken in case of their occurrence.

In addition, we establish a company-wide risk management system with President, Representative Director as the chief risk management officer and Executive Director, Corporate Strategy & Planning (Member of the Board of Directors, Executive Officer) as the risk management director in charge. In this way, we tackle issues related to risk management, recognizing them as important management strategic issues.

Establishment of the Enterprise Risk Management (ERM) System

We started preparations for the introduction of Enterprise Risk Management (ERM) in FY2018 and introduced it in FY2019, aiming for total, rather than partial, optimization of risk management.

For implementation, we have appointed a Chief Risk Management Officer (President, Representative Director, and Chief Executive Officer) and a Head Risk Management Officer (Member of the Board of Directors, Executive Officer / Executive Director, Corporate Strategy & Planning) and newly established the "Risk Management Office." We also established the "Risk Management Regulations" in order to promote ERM.

〈Basic Policy on ERM〉

- (1) With the aim of ensuring stable business continuity and achieving our business objectives, we develop and implement an enterprise risk management system to minimize losses to our company and its stakeholders including customers, while fulfilling our accountability to society.
- (2) Each division assesses its risks and those in divisions under its jurisdiction, using the risk assessment sheet, and autonomously promotes risk management.
- (3) We identify the most important and urgent risks that could have a considerable impact on business management as material risks, and promote company-wide risk management activities.
- (4) In the event a risk materializes, we will take measures to minimize the damage and ensure prompt recovery in order to solve problems as quickly as possible.

〈ERM Promotion System〉

- (1) Basic Approach
 1. The Heads of each division supervises the risk management of the entire division through the division's Risk Management Promotion Meeting.
 2. Division Managers conduct daily risk management as risk owners.
 3. Every quarter, Risk Management Office monitors the risk management status of each division from the viewpoint of ERM.

The results of monitoring are shared and examined for issues at the Company-Wide Risk Management Committee (Chairperson: Director, Risk Management Office) held twice a year. The monitoring results are also reported to the Management Committee (Composed of directors, executive officers, division managers, etc.) and the Board of Directors.

(2) Risk Management Promotion Meeting

The Risk Management Promotion Meeting in each division assesses the risks of their division and extracts issues using the risk assessment sheet, and develops prevention measures for identified risks according to their materiality and urgency, as well as risk response plans. Thus, each division autonomously promotes risk management by considering, developing and implementing appropriate risk measures. The risk assessment sheet covers a wide range of risks, not only business risks, but also risks related to the environment, major disasters, human rights, pharmaceutical affairs laws and regulations, and bribery, etc.

(3) Response to Material Risks

The Management Meeting identify important and urgent risks as "material risks" every fiscal year, and consider, develop and implement measures to control the identified risks, while monitoring the identified risks on a company-wide scale.

In the event a risk arises, we will take action in accordance with the response plan to minimize the damage and ensure prompt recovery, thereby solving problems as quickly as possible.

(4) Crisis Management

In the event a material risk arises and crisis management becomes necessary, the President will appropriately establish an Emergency Response Committee to take measures to minimize damage and facilitate speedy recovery.

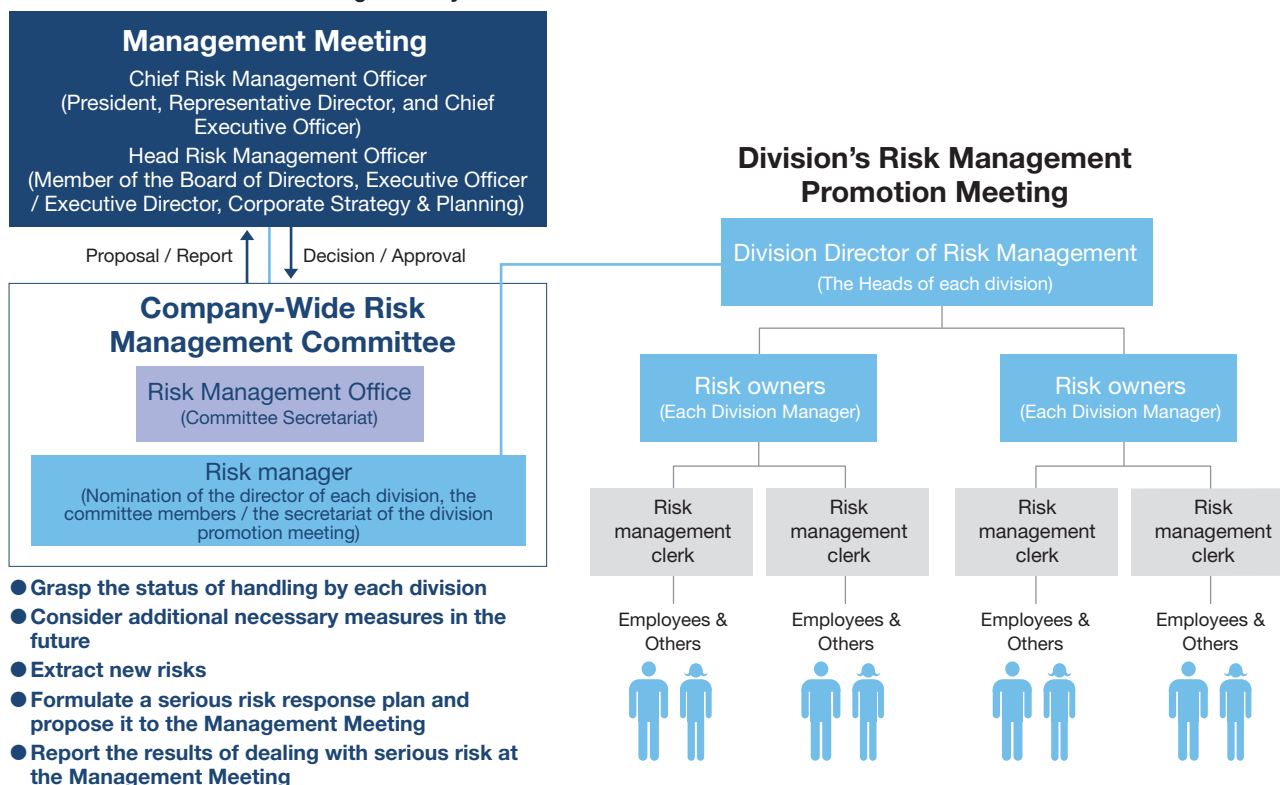
(5) Risk Management Education

We provide education on risk management for all employees to raise their awareness and sensitivity toward risks. In FY2019, we conducted e-learning training to help employees acquire basic knowledge about risks, risk assessment, and ERM, and learn about our company's ERM system. In addition, we started to provide workshop-type training for directors and leaders. We continue to promote education on various kinds of risk management.

ONO Group's Risk Management

To promote risk management activities across the Group, we provide our subsidiaries with guidance and advice on risk management, while respecting their autonomy. We provide such guidance and advice through various opportunities including regular meetings where we receive reports from subsidiaries regarding their business operations and discuss important matters. We are currently working to expand our ERM system to our subsidiaries in Japan and overseas by the end of FY2020 to further enhance the risk management of the entire Group.

ONO Pharmaceutical's Risk Management System



Business Continuity Plan (BCP)

According to the instructions of the Emergency Response Committee chaired by the President, Representative Director, we have organized the BCP Management Headquarters and established a system designed to minimize the impact of an emergency on mission-critical operations even in the case where an emergency occurs such as a natural disaster or serious accident, so that we can continue business activities or recover promptly and resume them if they are suspended. The BCM Committee, which is chaired by Executive Director, Corporate Strategy & Planning (Member of the Board of Directors, Executive Officer) and in charge of business continuity management (BCM), and the Management Office have been formed to maintain and strengthen our abilities to respond to crisis and continue our business operations, and promote relevant management activities during normal times. We have installed systems prepared for disasters such as emergency generators and duplicate power service in our head office building, the Tokyo Building, and all of our plants and research institutions, and we also have introduced seismic isolation systems to prepare for earthquakes in our head office building, the Tokyo Building, Minase Research Institute, and Yamaguchi Plant. As we have transferred some of the Osaka Head Office's functions to the Tokyo Building, the development of our two-base system prevents us from having to stop our business activities and improves our ability to continue our business operations.

▶ BCP System

<https://ono-csr.disclosure.site/en/themes/102#922>

TOPICS

Actions against the Novel Coronavirus Infectious Disease (COVID-19)

In order to achieve our social mission as a life-related pharmaceutical company, we have been maintaining stable supply of drugs in cooperation with relevant companies and customers. Therefore, the production and supply system of ONO's drugs has had no problems for the moment. In addition, to contribute to research and development of therapeutic products, etc., we started clinical trials using oral protease inhibitors, camostat mesilate, and we have also provided agents for clinical research at the request of medical institutions and research institutions in and outside Japan.

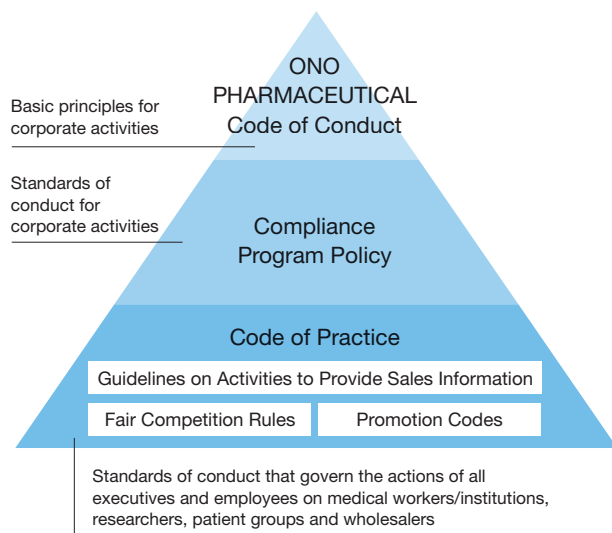
In addition, with the aim of preventing the expansion of infections, we have refrained from visiting medical institutions; however, we are now transferring to a system where we can provide information to healthcare personnel and collect drug safety information even under a telework environment. In June 2020 and after, we started marketing activities step by step from areas and medical institutions that have a small impact and we are engaging in information provision activities by using new means, such as planning interviews using websites or planning remote lectures, etc.

Compliance

ONO PHARMACEUTICAL'S Compliance System

Being aware of responsibilities as a pharmaceutical company dealing in pharmaceuticals upon which human lives depend, ONO PHARMACEUTICAL has the ONO PHARMACEUTICAL Code of Conduct to ensure that it acts in compliance with laws and regulations and that it meets high ethical standards. Our compliance system consists of the ONO PHARMACEUTICAL Code of Conduct as basic guidelines for corporate activities, the Compliance Program Policy as a behavioral standard for its activities, and the Code of Practice based on pharmaceutical industry standards related to promotional activities.

In practicing the compliance system, we are repeatedly informing our employees about ensuring transparency, preventing fraud and corruption, constantly being conscious of domestic and international social conditions.



- ▶ ONO PHARMACEUTICAL Code of Conduct
<https://www.ono.co.jp/eng/about/conduct.html>
- ▶ ONO PHARMACEUTICAL Compliance Program Policy
<https://ono-csr.disclosure.site/en/themes/116#940>
- ▶ ONO PHARMACEUTICAL Code of Practice
<https://ono-csr.disclosure.site/en/themes/116#988>

Compliance Promotion System

To promote compliance, we have appointed a Corporate Compliance Officer and set up a Corporate Committee. The Corporate Committee examines and deliberates on compliance-related issues, plans and promotes relevant training programs, and checks to what extent such compliant related matters are shared and understood within the company in

cooperation with the internal auditing department.

We have internal and external contacts, such as a 24-hour external contact service named the ONO Hotline, which was set up in 2015 for compliance issues as well as a system to ensure that informants can directly report to or consult with top management—that is, the Representative Director, the Corporate Compliance Officer, and the Corporate Auditors. Under this system, compliance violations including harassment can be prevented, appropriate work environment can be ensured, and necessary measures can be taken to minimize any loss of credibility in the event of a compliance violation. We ensure that the matters including informant's name, reported content, and his/her privacy are strictly kept confidential to other than those involved in the survey, and support anonymous reporting. In addition, we will never bring detriment to such an informant solely because of use of the system. This system has been certified as a Whistleblowing Compliance Management System (WCMS) (a system for self-declaration of conformity).

In particular, with regard to prevention of harassment, not only do we provide training courses for management staff every year, but we also include harassment and other issues in the sessions conducted by external lecturers, thereby enhancing awareness of compliance.

We provide guidance to companies in creating systems and rules to prevent the occurrence of noncompliance, and we strongly urge our affiliates and suppliers to do the same. We also continue enhancing the system to make the contacts available in the entire group so that employees can report or consult without hesitation.

▶ Reporting and Consultation System

<https://ono-csr.disclosure.site/en/themes/101#918>

Ethical Considerations

ONO always gives consideration to ethical treatment in various stages of research and development.

We conduct research using human specimens (blood, tissue, cells, genes, etc.) after strict deliberations on ethical and scientific acceptability. To this end, we have established internal ethical codes based on the basic guidelines specified by the Japanese government and set up the Ethics Committee for Medical and Health research Involving Human Subjects composed of internal and external members as an advisory board.

To ensure that the lives of the animals are respected and proper consideration is made to animal welfare in research using laboratory animals, we have established the Institutional Animal Care and Use Committee that reviews whether all animal experimental protocols are prepared based on the principles of the 3Rs—Replacement (active use of alternative methods of experiment), Reduction (reducing the number of animals used), and Refinement (alleviation of pain)—in advance. The Committee also implements self-inspections and assessments of the animal experiment processes and ONO obtained certification for these activities from a third party, the Center for Accreditation of Laboratory Animal Care and Use (CALAC) of the Japan Health Sciences Foundation (JHSF).

Clinical trials, which are essential for verifying the safety and

efficacy of investigational compounds, must be performed with respect for the rights of trial subjects. Clinical trials are closely monitored for patients' safety and are stringently conducted under high ethical standards. We are committed to evaluating the real value of investigational compounds by steadily applying essential and complete testing procedures that comply with the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices of Japan (Pharmaceutical and Medical Device Act) and other related legislation, as well as the global standards based on the spirit of the Declaration of Helsinki.

In the past, inadequate safety monitoring performance for pharmaceuticals caused many drug disasters. We periodically carry out education on drug-induced toxicity for all employees so that we will not forget the patients' pain, the misery of drug disasters, and the magnitude of corporate responsibility.

- ▶ Considerations to ensure the human rights of research subjects

https://www.ono.co.jp/eng/rd/human_rights.html

- ▶ Ethical considerations in the use of animals

https://www.ono.co.jp/eng/rd/animal_ethics.html

Fair and Transparent Business Activities

In order to conduct fair and transparent business activities, we have established a training month for providing e-learning and training in each division every year to provide education thoroughly to all employees concerning the prevention of fraud and corruption.

We aim to contribute to healthcare all around the world and people's health through continuous R&D activities and the stable supply of new drugs. To this end, we need to engage in collaborative activities—for example, providing support for patient groups—and cooperate with research and medical institutions to help patients overcome disease and pain. To enhance the fairness and transparency of such collaborations and cooperation, 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 groups in accordance with our transparency guidelines, which are formulated in line with the relevant guidelines of the Japan Pharmaceutical Manufacturers Association (JPMA).

Regarding tax compliance, ONO has established the ONO PHARMACEUTICAL Global Tax Policy and is striving to engage in rigorous activities under the responsibility of the Member of the Board of Directors, Executive Officer / Executive Director of Corporate Strategy & Planning who is the Corporate Compliance Officer.

While compliance with laws related to fraud and corruption is attracting increasing attention on a global scale, we established ONO PHARMACEUTICAL Global Anti-Bribery and Corruption Policy and the Regulations on Bribery Prevention in 2017 to clarify our bribery prevention system in a written form, and work to operate them in a strict manner. Furthermore, we support Transparency International's Business Principles for Countering Bribery, an international anti-bribery standard. No facilitation

payment defined the Global Policy was exercised in FY2019.

To ensure that publicly funded research is conducted in compliance with the relevant guidelines established by the Japanese government, we have formulated the Action Guidelines for Publicly Funded Research and the Regulations on Publicly Funded Research, and apply them for even more appropriate use and management of public research funds.

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

<https://www.ono.co.jp/jpnw/about/torikumi.html>

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

<https://www.ono.co.jp/jpnw/about/kanjya.html>

- ▶ Operation and Management System of Public Research Fund

<https://www.ono.co.jp/eng/rd/management.html>

- ▶ ONO PHARMACEUTICAL Global Tax Policy

<https://ono-csr.disclosure.site/en/themes/116#991>

- ▶ ONO PHARMACEUTICAL Global Anti-Bribery and Corruption Policy

<https://ono-csr.disclosure.site/en/themes/116#941>

Proper Procurement Activities

ONO considers that establishing a sound network with all our suppliers in the supply chain is important for achieving the development of a sustainable society. We are promoting CSR Procurement under our "Basic Policy for Procurement Activities," which serves as a fundamental approach to procurement for all employees involved in procurement activities, and the "CSR Procurement Guidelines," which lists all of the items for which we seek cooperation from each of our suppliers.

In order to objectively and continually grasp the CSR-related circumstances of the most important suppliers in our supply chain, ONO has used the CSR evaluation system of EcoVadis. Use of the evaluation system enables us to obtain highly reliable information regarding supplier CSR management at least once a year, and to recommend appropriate corrective action to our suppliers. According to an assessment in FY2019, there were no companies with high CSR risks. We also hold instructional conferences for our suppliers regarding CSR in procurement in order to help them understand our ideas on procurement CSR and to strengthen our partnerships.

ONO will further develop the cooperation system through CSR procurement and aim to increase the company value of both ONO and its suppliers.

- ▶ Basic Policy for Procurement Activities and CSR Procurement Guidelines

<https://ono-csr.disclosure.site/en/themes/116#943>