Compliance Program Policy of Ono Pharmaceutical Co., Ltd.

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1. We will develop effective, safe, and high-quality pharmaceutical products that are useful in offering medical care to people and provide these products to society with necessary information.

(Explanation)
We are mindful of the phrase, “Dedicated to the Fight against Disease and Pain”, as our Corporate Philosophy.
We aim to develop innovative pharmaceutical products that are useful in the treatment of diseases for which we have no appropriate therapy, that are truly useful in treating patients and improving their quality of life (QOL), and that are helpful in the improvement of medical economic efficiency.
We will respect human rights and strive to secure the safety of all subjects that participate in clinical trials.
We will place importance on providing appropriate information on the efficacy and safety of products based on both the moral value that we are participating in preserving the sanctity of life and the objective evaluation as corroborated by the latest advancements in science.
We will make every effort to secure the high quality of our products while prioritizing the safety of patients.

<Compliance program-related items for this provision>

(1) Basic Stance

(1) We will not only abide by the laws and regulations when we act, but also adhere to high moral values including life ethics, as personnel of a life science company trading in products that serve to the health of people.
(2) We will always prioritize actions based on high moral values without being buried in “business logic,” and will not pursue profits as a company or accomplishments as an individual.
(3) We realize that we assume the final responsibility even for a task, a part of which is outsourced to a group company or contractor, in various stages of research, development, manufacture, sales, etc., of products. Therefore, we will explain our stance, etc., to the group company and contractor to perform the task with a sense of unity.

(Explanation/Supplement)
Today, individuals need to adhere to high morals in their capacity as company personnel and as members of society. In such circumstances, strict and high corporate morality is especially necessary for pharmaceutical companies that handle products related to human health and life.
High corporate morality refers to the act of strictly controlling ourselves with humility for science while prioritizing the sanctity of life. Each of us must be aware of our mission and control our behaviors.
We must always consider the divergence between social common sense and "business logic." We must choose ethically correct acts if there is any conflict between ethically correct acts and company profits

and/or individual accomplishments.

Reference laws and regulations: Law for Ensuring the Quality, Efficacy, and Safety of Drugs and Medical Devices (Pharmaceutical and Medical Device Act), etc.

Reference external standards, etc.: UN Global Compact (United Nations), Charter of Corporate Behavior (Japan Economic Federation), Code of Practices for Pharmaceutical Industry (Federation of Pharmaceutical Manufacturers' Associations of Japan (FPMAJ)), and the JPMA Promotion Code for Prescription Drugs (Japan Pharmaceutical Manufacturers Association (JPMA)), etc.

(2) Drug Discovery and Exploratory 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 laws and regulations.

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

(3) We will comply with the Infectious Disease Law, the Act on Domestic Animal Infectious Diseases Control, etc., to prevent biohazard accidents caused by pathogens, etc.

(4) While conducting animal experiments, we will comply with related laws, regulations, notifications, 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.

(Explanation/Supplement)

There is a risk of handling substances that are synthesized or obtained externally in the processes of drug discovery research without knowing that they are regulated by laws and regulations. It is necessary to establish a system to constantly check the revision of applicable laws and regulations and can always confirm whether or not a substance is a controlled one.

Research on human genes, etc., and genomic drug discovery must also be conducted respecting the sanctity of life and human rights with thorough informed consent/protection of personal information, establishment/operation of a fair and neutral ethical review board, etc. In gene modification experiments, regulations of gene-modified organisms, etc., must be complied with to prevent adverse effects on the preservation of biodiversity and sustainable use. In addition, while handling pathogenic microorganisms of infectious livestock diseases, the Act on Domestic Animal Infectious Diseases Control must be complied with to prevent leakage from the control area.

While conducting animal experiments, we will not forget that research and development of drugs are conducted at the expense of animals and adhere to the "3Rs Principles," that is, making efforts to alleviate of pain (Refinement), reduce the number of test animals (Reduction), and actively use of alternative methods of experiment (Replacement).

Reference laws and regulations: Act on Regulation of Human Cloning Techniques, Act on the Protection of Personal Information (Private Information Protection Law), Law Concerning Prevention from Radiation Hazards due to Radioisotopes, etc., Narcotics and Psychotropics Control Act, Opium Act, Stimulants Control Act, Cannabis Control Act, Act Concerning Special Provisions for the Narcotics and Psychotropics Control Act, etc., and Other Matters for the Prevention of Activities Encouraging Illicit Conduct and Other Activities Involving Controlled Substances through International Cooperation, Law for Ensuring the Quality, Efficacy, and Safety of Drugs and Medical Devices (Pharmaceutical and Medical Device Act), Poisonous and Deleterious Substances Control Act, Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc., Industrial Safety and Health Act, Fire Service Act, Basic Act on Biodiversity, Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Cartagena Law), Act Concerning Prevention of Infection of Infectious Diseases and Patients with Infectious Diseases (Infectious Disease Law), Act on Domestic Animal Infectious Diseases Control, Act on Improving the Capacity, and the Efficient Promotion of Research and Development through Promotion of Research and Development System Reform, Act on Welfare and Management of Animals, etc.

Reference external standards, etc.: Standards Relating to the Care and Management of Laboratory Animals and Relief of Pain (Ministry of the Environment Notice), Guidelines for the Euthanasia of Animals (Ministry of the Environment Notice), Guidelines for Responding to Ethical Issues, etc. Associated with Gene Analysis Research (Advanced Medical Technology Evaluation Committee, Health Science Council of MHLW), Fundamental Principles of Research on the Human Genome (Life Ethics Committee, Council for Science and Technology), Ethical Guidelines for Medical and Health Research Involving Human Subjects (Ministry of Education, Culture, Sports, Science and Technology (MEXT)), etc.

(3) Clinical Trial

(1) We will conduct clinical trials in compliance with laws and regulations including the Pharmaceutical and Medical Device Act and Ministerial Ordinance on Good Clinical Practice for Drugs (GCP), 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) We will respect the human rights of the subjects of clinical trials to the maximum extent possible while conducting the trials. Necessary information will be provided 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 fraud such as the falsification and concealment of data. We will not require such frauds to contractors, joint research institutions, etc.

(4) We will appropriately disclose clinical trial information and information on expenses to conduct clinical trials in accordance with voluntary industry codes to improve transparency.

(Explanation/Supplement)

(1) Compliance with rules, such as GCP, etc., is the major premise for clinical development and is a responsibility imposed on pharmaceutical companies. Prior to the start of a clinical trial that imposes a burden on subjects, data obtained up to that point must be examined thoroughly. Investigational drugs

shall be provided only after confirming that they are sufficiently beneficial for patients.
(2) Subjects of clinical trials are humans. It is natural that rules and procedures including GCP are complied with to ensure the protection of human rights and the safety of the subjects. If any adverse drug reactions, etc., occur, the safety of the subjects must be prioritized. We will establish an internal system to respond to cases where health damage occurs in subjects.
(3) In conducting clinical trials, we will prepare objective and accurate data on the efficacy and safety of drugs, etc., and will not engage in any form of fraud such as falsification or concealment of data. We will not require such frauds to contractors, joint research institutions, etc.
(4) To ensure the transparency of clinical trial information, such information must be disclosed in accordance with the "Joint Position on Clinical Trial Information Disclosure via Clinical Trial Register and Database (2018)" and "Joint Position on the Publication of Clinical Trial Results in the Scientific Literature (2010)" which are joint guidelines of JPMA, International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), European Federation of Pharmaceutical Industries and Associations (EFPIA), and Pharmaceutical Research and Manufacturers of America (PhRMA), etc. Further, information on the provision of expenses to conduct clinical trials must be disclosed in accordance with the "Transparency Guidelines for the Relation between Corporate Activities and Medical Institutions" of JPMA.

Reference laws and regulations: Law for Ensuring the Quality, Efficacy, and Safety of Drugs and Medical Devices (Pharmaceutical and Medical Device Act), Ministerial Ordinance on Standards for the Implementation of Clinical Trials on Pharmaceutical Products (GCP), Ministerial Ordinance on Standards for the Implementation of Clinical Trials on Regeneration Therapy Products, Good Manufacturing Practice for Investigational Products (GMP for Investigational Products), Penal Code, National Public Service Ethics Act, Rules of Ethics for Government Officials, Act on the Protection of Personal Information (Private Information Protection Law), etc.

Reference external standards, etc.: Declaration of Helsinki, Ethical Guidelines for Medical and Health Research Involving Human Subjects (MEXT and MHLW), Joint Position on Clinical Trial Information Disclosure via Clinical Trial Register and Database (IFPMA, EFPIA, JPMA, and PhRMA), Joint Position on the Publication of Clinical Trial Results in the Scientific Literature (IFPMA, EFPIA, JPMA, and PhRMA), COI Management Guidelines for Clinical Research (Japan Medical Association), etc.

(4) Application for Approval

While applying for drug 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, notifications, etc., and internal rules. If any survey or study results, etc., that suspect the quality, efficacy, or safety of a drug applied are obtained, they will be examined and evaluated and the results will be described in the application materials without any fraud such as the falsification, replacement, or concealment, etc., of the materials. If such studies, etc., are conducted by group companies or contractors, the implementation of the studies, etc., shall be adequately supervised to ensure that the implementation of the studies, etc., and the acquisition of data are conducted appropriately.

(Explanation/Supplement)

It is a natural premise that marketing approval for drugs that are directly related to human health shall be given through a fair review by the government for application materials that are prepared based on results of surveys or studies conducted in compliance with related laws, regulations, notifications, etc., and internal rules and the reliability of which is secured. There is no need to say that this is the basis of people's trust in drugs. If any survey or study required to prepare application materials is conducted in an improper manner or if any application materials are modified, replaced, or concealed, it may cause direct harm to the health of people in addition to a fundamental loss of trust in the drug approval system and pharmaceutical companies. As a pharmaceutical company, we always need to act with the understanding that this is impermissible.

Reference laws and regulations: Law for Ensuring the Quality, Efficacy, and Safety of Drugs and Medical Devices (Pharmaceutical and Medical Device Act), Ordinance for Enforcement of the Pharmaceuticals and Medical Devices Act, Ministerial Ordinance on Good Manufacturing Practice for Drugs and Quasi-drugs (GMP), Ministerial Ordinance Concerning the Standards for the Conduct of Non-clinical Studies on the Safety of Drugs (GLP), Ministerial Ordinance on the Standards for the Implementation of Clinical Trials on Pharmaceutical Products (GCP), etc.

(5) Post-marketing Safety Measures, 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 the laws and regulations, including the Pharmaceutical and Medical Device Act, Ministerial Ordinance on Good Vigilance Practice for Drugs, Quasi-drugs, Cosmetics, Medical Devices, and Regenerative Medicine Products (GVP), and Ministerial Ordinance on Good Post-marketing Study Practice for Drugs (GPSP), and internal operating procedures.

(2) If we suspect that any adverse event has occurred because of our products, we will promptly report it to the authorities in accordance with the laws, regulations, and internal operating procedures and take safety assurance measures as necessary.

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

(Explanation/Supplement)

Regardless of whether the operations are domestic or overseas, we must always look at safety management information on our products and those of the same category, promptly evaluate the information obtained, appropriately report it to the authorities, and provide it to healthcare professionals as necessary.

There are limitations for the confirmation of efficacy and safety in the development stage. We must establish a system to collect and evaluate post-marketing safety management information and ensure safety and efficacy.

To ensure the safety of drugs, it is important to manage risks properly at all times right from the development to post-marketing stages. A Risk Management Plan (RMP) summarizes the consistent risk management requirement from the drug development to the post-marketing stages in one document in an easy-to-understand manner to ensure that the evaluation is conducted either according to the progresses of post-marketing surveillance and efforts to reduce risks, or periodically. We must strengthen post-marketing safety measures further by publicizing the RMP as necessary to share the

contents of risk management with healthcare professionals.
MRs must not be involved in the preparation of surveillance sheets in post-marketing surveillance conducted based on contracts with medical institutions. Medical institutions must not be asked for post-marketing surveillance for the purpose of inducing adoption or prescription of products.

Reference laws and regulations: Law for Ensuring the Quality, Efficacy, and Safety of Drugs and Medical Devices (Pharmaceutical and Medical Device Act), Ministerial Ordinance on Good Vigilance Practice for Drugs, Quasi-drugs, Cosmetics, Medical Devices, and Regenerative Medicine Products (GVP), Ministerial Ordinance on Good Post-marketing Study Practice for Drugs (GPSP), Ministerial Ordinance on Good Post-marketing Study Practice for Regenerative Medicine Products, etc.

Reference external standards, etc.: Operation Standards for Implementation of Case Report Collection Plan (Fair Trade Council of the Ethical Pharmaceutical Drugs Marketing Industry), etc.

(6) Clinical Research

(1) In support of clinical research, we will comply with the Clinical Research Act, Ethical Guidelines for Medical and Health Research Involving Human Subjects, Fair Competition Rules, and other laws, regulations, voluntary industry codes, 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 based on the Clinical Research Act and voluntary industry codes.

(Explanation/Supplement)
In support of clinical research, it is the responsibility of pharmaceutical companies to comply with laws and regulations, such as the Clinical Research Act, Ethical Guidelines for Medical and Health Research Involving Human Subjects, Fair Competition Rules, voluntary industry codes, etc. Before supporting clinical research, it is necessary to thoroughly examine the data obtained so far, to determine the ethical and scientific validity of the clinical research, and to judge the necessity to support it.
In support of clinical research using a company's pharmaceutical products, it is necessary to clarify the responsibilities of each party, conclude a written contract with researchers/medical institutions, and provide funds clearly and fairly in accordance with the Clinical Research Act, etc.
To ensure the transparency of clinical research, information must be disclosed in accordance with the Clinical Research Act or "Transparency Guidelines for the Relation between Corporate Activities and Medical Institutions" of JPMA.
When providing benefits/labor services for clinical research, it is necessary to pay attention to conflicts of interest and pay careful attention so that the reliability of clinical research results will not be questioned.

Reference laws and regulations: Clinical Research Act, etc.

Reference external standards, etc.: Ethical Guidelines for Medical and Health Research Involving Human Subjects (MEXT/MHLW), Fair Competition Rules for Drugs (Fair Trade Council of the Ethical Pharmaceutical Drugs Marketing Industry), Joint Position on the Publication of Clinical Trial Results in the Scientific Literature (IFPMA, EFPIA, JPMA, and PhRMA), Transparency Guidelines for the Relation between Corporate Activities and Medical Institutions (JPMA), COI

Management Guidelines for Clinical Research (Japan Medical Association), etc.

(7) Manufacturing and Import/Export

(1) We recognize that our products are life-related products and will provide stable supply 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, notifications, etc., and internal rules, conduct appropriate manufacturing and quality control throughout the entire manufacturing process (including processes at group companies or 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, notifications, etc., and internal rules.

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

(Explanation/Supplement)

We must always be aware that we are handling products related to human life. Our mission is to ensure that the opportunity to provide adequate treatment to patients is not hindered by the stockout of products, etc. Manufacturing and quality control must be performed according to the approval certificate in compliance with standards for manufacturing and quality control from the stage of receipt of raw materials to the stage of packaging and release of finished products. All processes, including those at group companies or contract manufacturers, must be performed under organizational control. International standards must also be complied with following the progression of borderlessness and globalization.

Accidents and disasters such as fires, explosions, etc., in plants and manufacturing facilities may jeopardize employees (in this paragraph, all persons working at plant premises are included) and surrounding residents and may contaminate the environment in the surrounding areas. To prevent such problems, it is necessary to comply with related laws, regulations, notifications, etc., and internal rules, while sufficiently confirming whether safety and operating procedures of a plant and manufacturing equipment are appropriate, and take measures to prevent the expansion of damage in the event of accidents or disasters. In addition, it is necessary to comply with related laws, regulations, notifications, etc., and internal rules in handling chemical substances used in production activities and plant effluents/exhausts.

Drugs, etc., shall be appropriately received and stored in facilities with drug wholesale business licenses to ship/transport to wholesalers, medical institutions, etc. At the time of acceptance, it must be confirmed that they are provided through a proper supply chain and the entering of counterfeit medicines must be prevented. For storage, requirements related to regulatory classification and storage conditions (temperature control) must be met. For shipment/transportation, appropriate cargo handling and transportation business operators must be selected, and efforts must be made to improve their knowledge to prevent accidents, defacement/damage, theft, loss, damage to health and hygiene, etc.

For export, the Foreign Exchange and Foreign Trade Act and other related laws, regulations, notifications, etc., and internal rules must be complied with.
For import, an import license must be acquired based on the Law for Ensuring the Quality, Efficacy, and Safety of Drugs and Medical Devices and Poisonous and Deleterious Substances Control Act, and procedures based on equivalent related laws, regulations, notifications, etc., and internal rules must be implemented appropriately.

Reference laws and regulations: Law for Ensuring the Quality, Efficacy, and Safety of Drugs and Medical Devices (Pharmaceutical and Medical Device Act), Ministerial Ordinance on Quality Control Standard for Drugs, Quasi-drugs, Cosmetics, and Regeneration Therapy Products (GQP), Ministerial Ordinance on Good Manufacturing Practice for Drugs and Quasi-drugs (GMP), Good Manufacturing Practice for Investigational Products (GMP for Investigational Products), Ministerial Ordinance on Manufacturing Control and Quality Control of Tissue-engineered Medicinal Products (GCTP), Product Liability Act, Warehousing Business Act, Poisonous and Deleterious Substances Control Act, Environmental Basic Act, Basic Act on Biodiversity, Act for the Settlement of Environmental Pollution Disputes, Act on Compensation, etc. of Pollution-related Health Damage, Air Pollution Control Act, Water Quality Pollution Control Act, Noise Regulation Act, Vibration Regulation Act, Offensive Odor Control Act, Wastes Disposal and Public Cleansing Act, Environmental Pollution Control Expense Sharing Act, Act on Evaluation of Effects on the Environment, Act for the Punishment of Environmental Pollution Crimes relating to Human Health, Act for Prevention of Soil Contamination in Farmland, etc., Act for Protection of the Ozone Layer through Regulation of Designated Substances, etc., Nature Conservation Act, Act for the Prevention of Marine Pollution and Maritime Disasters, Soil Contamination Countermeasures Act, Act on Special Measures concerning Countermeasures against Dioxins, Act on Promotion of Global Warming Countermeasures, Act on Rational Use and Appropriate Management of Fluorocarbons, Act for Protection of the Ozone Layer through Regulation of Designated Substances, etc., Sewerage Service Act, Act on Special Measures concerning the Proper Treatment of Polychlorinated Biphenyl Waste, Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc., Act on the Prohibition of Chemical Weapons and the Regulation of Specific Chemicals, Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof, Act for the Establishment of Pollution Prevention Systems in Specified Factories, Fire Service Act, High Pressure Gas Safety Act, Act on Special Measures concerning the Conservation of the Environment of the Seto Inland Sea, Industrial Safety and Health Act, Narcotics and Psychotropics Control Act, Stimulants Control Act, Opium Act, Cannabis Control Act, Measurement Act, Product Liability Act, Road Trucking Vehicle Act, Road Traffic Act, Warehousing Business Act, Poisonous and Deleterious Substances Control Act, Foreign Exchange and Foreign Trade Act, Customs Act, Customs Tariff Act, Act on Temporary Measures concerning Customs, Export and Import Trading Act, Marine Transportation Act, Act for International Carriage of Commodities by Sea, Narcotics and Psychotropics Control Act, Stimulants Control Act, Fire Service Act, Industrial Safety and Health Act, Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Cartagena Law), etc.

Reference external standards, etc.: Convention on International Trade of Endangered Species of Wild Fauna and Flora (Washington Convention), etc.

(8) Medical Information Activities

(1) In conducting medical information activities for medical institutions, etc., we will conduct activities with fairness and transparency in compliance with the Fair Competition Code Concerning Distinction on Premium Offers in Ethical Drugs Marketing Industry, Promotion Code, etc.

(2) We will acquire the medical and pharmaceutical knowledge necessary for medical information activities and provide appropriate information on drugs to improve and promote the health of patients and general consumers in accordance with laws, regulations, etc.

(3) We provide information on our products to healthcare professionals within the scope of marketing approval.

(4) In relation to physicians, pharmacists, etc., at medical institutions that are independent administrative entities, we will maintain a healthy relationship so as not to violate or be suspected of violating the provisions of law addressing bribery in the Penal Code, National Public Service Ethics Act, and other ethical laws, regulations, and standards.

(Explanation/Supplement)

(1) Pharmaceutical companies must take responsibility for ethical and sincere interactions with healthcare professionals, etc. It must be recognized that medical information activities are a venerable mission to accurately communicate drug information responsible for the proper use of drugs. Therefore, while interacting with researchers, healthcare professionals, etc., it is necessary to conduct fair and transparent activities in compliance with the Pharmaceutical and Medical Device Act, Antimonopoly Law, Fair Competition Rules, JPMA Code of Practice, etc.

(2)While providing information on our company's products to healthcare professionals, etc., information on indications, dosage, and administration, etc., will be provided within the scope of marketing approval. Objective information based on the latest data with clear scientific grounds must be provided with an easy-to-understand content/expression without using false or exaggerated expressions and in an appropriate manner without any bias in all aspects of efficacy, safety, etc. Materials used for medical information activities must be prepared in accordance with related laws, regulations, notifications, etc., and voluntary industry codes and internal rules.

(3) Medical information activities will also comply with the anti-bribery provisions of the Penal Code, National Public Service Ethics Act, etc.

Note: "Medical information activities" refers to collecting and providing information on the quality, efficacy, and safety of drugs, etc., and other information necessary for the proper use of drugs, etc., by visiting healthcare professionals, etc., to contribute to the proper use of drugs, etc.

Reference laws and regulations: Act on Prohibition of Private Monopolization and Maintenance of Fair Trade (Antimonopoly Act), Law for Ensuring the Quality, Efficacy, and Safety of Drugs and Medical Devices (Pharmaceutical and Medical Device Act), Product Liability Act, Penal Code, National Public Service Ethics Act, Rules of Ethics for Government Officials, etc.

Reference external standards, etc.: Standards for Fair Advertising Practices of Drugs, etc. (Notification from the Director of the Pharmaceutical Safety and Environmental Health Bureau, MHLW), Guidelines for Activities to Provide Sales Information of Ethical Drugs (MHLW), Fair Competition Rules for Drugs (Fair Trade Council of the Ethical Pharmaceutical Drugs Marketing

Industry), JPMA Code of Practice (JPMA), Guidelines for Preparation of Ethical Drug Product Information Brochure, etc. (JPMA), IFPMA Guidance on Proper Competition (IFPMA), etc.

2. We will respect the human rights of all people in every aspect of our business activities

(Explanation)
We value a society where human rights are respected and think that people must not be discriminated against on grounds of nationality, ideology, religion, education, or gender within and outside the company.
We will actively support positive approaches of employees to develop abilities without fearing failure and will aim to create a company environment where the capacity of individuals is maximized and the company and personnel can coexist, on the premise that "Business is people."
We will respect and not infringe the privacy of personal information obtained in the course of business within or outside the company.

<Compliance program-related items for this provision>

(1) Human Rights

We understand and respect human rights, various philosophies, personalities, and characters of each personnel and will not discriminate against or harass them on grounds of nationality, race, belief, gender, social status, disability, appearance, etc. We will also express our respect for human rights, etc., to the supply chain and ask for their understanding.

(Explanation/Supplement)
We need to understand internationally recognized norms on human rights, to respect the philosophy and personality of each individual, not to conduct any discriminatory action in any situation, and to interact with each other as humans regardless of the differences in their positions and roles.
We are required by society to clarify the policy on human rights, etc., and establish a system to reflect it in our business activities. We are also required to express our respect for human rights, etc., to entities constituting supply chains such as suppliers, request their understanding while also actively supporting them so that appropriate approaches are taken at all levels. If our business activities impact human rights negatively, corrective actions will be taken promptly.

Reference laws and regulations: Constitution of Japan, Labor Standards Act, Act for Securing the Proper Operation of Worker Dispatching Undertakings and Improved Working Conditions for Dispatched Workers (Worker Dispatch Law), Equal Employment Opportunity Law, etc.

Reference external standards, etc.: Universal Declaration of Human Rights/International Covenants on Human Rights/Guiding Principles on Business and Human Rights (United Nations), Guidelines for Multinational Enterprises (OECD), Tripartite Declaration of Principles concerning Multinational Enterprises and Social Policy (ILO), etc.

(2) Prohibition of Unfair Discrimination and Harassment

(1) We will not discriminate against or harass people on grounds of race, nationality, ethnicity, gender, age, religion, philosophy, ideology, sexual orientation/self-recognition, education, disability,

disease, etc., for employment, treatment, promotion, etc.
(2) We will not allow harassment in the workplace and will strive to respect the personality of workers and create a pleasant working environment.

(Explanation/Supplement)
As declared in the Universal Declaration of Human Rights, every person has the right to live freely without any discrimination. Even within the company, there must be no discrimination in all aspects including the workplace environment, employment conditions, employment opportunities, etc. In addition, harassment prevents employees from maximizing their abilities and must therefore never be done.
There are many forms of harassment: power, maternity, paternity, moral, age, academic ("power-related harassment utilizing the workplace position"), sexual, gender, and marriage harassment ("sex/racial discrimination-related harassment"). We need to be aware of these forms of harassment and take appropriate action, including the protection of victims.

Reference laws and regulations: Constitution of Japan, Labor Contract Act, Labor Standards Act, Act on Securing, etc. of Equal Opportunity and Treatment between Men and Women in Employment, Act for Securing the Proper Operation of Worker Dispatching Undertakings and Improved Working Conditions for Dispatched Workers (Worker Dispatch Law), Basic Act for the Disabled Persons, Act on Employment Promotion, etc. of Persons with Disabilities, Act on Childcare Leave, Caregiver Leave, and Other Measures for the Welfare of Workers Caring for Children or Other Family Members, Act for Stabilization, etc., of Employment of Older Persons, etc., Whistle-Blower Protection Act, Law on Proscribing Stalking Behavior and Assisting Victims, etc.

Reference external standards, etc.: Universal Declaration of Human Rights/International Covenants on Human Rights/Guiding Principles on Business and Human Rights (United Nations), Guidelines Concerning Measures to be Taken by Employers in terms of Employment Management with Regard to Problems Caused by Sexual Harassment in the Workplace (MHLW), Recommendations for Prevention and Resolution of Power Harassment in the Workplace (MHLW), Guidelines for Measures to be Taken from the Viewpoint of Employment Management for Problems Caused by Words and Actions of Employer for Pregnancy, Childbirth, etc. (MHLW), etc.

(3) Compliance with Labor Law and the Approach toward Creating a Pleasant Working Environment

(1) We will comply with the Labor Standards Act, the Industrial Safety and Health Act, and other labor-related laws and regulations. We will also create a working environment with due consideration for safety and health and a flexible working environment to prevent industrial accidents and to maintain the health of employees.
(2) We understand the purpose of the Health Promotion Act and will promote measures to prevent passive smoking in the workplace, etc.

(Explanation/Supplement)
In order for us to demonstrate our ability and work with job satisfaction, we need a friendly working environment. In addition to protecting the safety and health of all personnel at work, it is also necessary to create a workplace environment that is comfortable and easy to work in.

"Ease of working" is largely concerned with the good balance between work and private life (work-life balance) and considerations wherein “work and childcare” and “work and nursing care” can be compatible.
In order for us to maximize our ability, we need to make efforts to enhance the working environment further. One of them is including options such as homeworking, etc., since it is thought of as being helpful in incorporating flexible working styles for staff, etc.

Reference laws and regulations: Labor Contract Act, Labor Standards Act, Act for Securing the Proper Operation of Worker Dispatching Undertakings and Improved Working Conditions for Dispatched Workers (Worker Dispatch Law), Industrial Safety and Health Act, Part-Time Employment Act, Work Environment Measurement Act, Act on Maintenance of Sanitation in Buildings, Labor Union Act, Labor Relations Adjustment Act, Health Insurance Act, Workmen's Accident Compensation Insurance Act, Act on Childcare Leave, Caregiver Leave, and Other Measures for the Welfare of Workers Caring for Children or Other Family Members, Act for Stabilization, etc. of Employment of Older Persons, etc., Employment Security Act, Health Promotion Act, etc.

Reference external standards, etc.: Guidelines for Smoking Control in Workplaces (MHLW), Standards for Classification between Worker Dispatching Business and Contract Business (Department of Labor Notice), etc.

(4) Implementation of Fair Personnel Evaluation

We will comply with the Labor Standards Act, employment-related laws, regulations, notifications, etc., and internal rules to promote appropriate job assignment and personnel exchange and conduct fair personnel evaluation. We will not treat some people favorably in staffing, personnel evaluation, or promotion because of our close relationships with them.

(Explanation/Supplement)
In order for the company to grow, it is necessary that personnel policies, such as personnel allocation, personnel evaluation, etc., are appropriately implemented so that each employee can achieve their maximum potential and develop their individual abilities. Even if an employee maximizes his/her ability in his/her work, it will not lead to his/her growth unless he/she receives a fair evaluation of his/her work without arbitrariness. If there is no proper staffing system, the personnel will not be able to demonstrate their individual capabilities fully.
We will endeavor to evaluate each employee fairly and ensure appropriate staffing.

Reference laws and regulations: Labor Standards Act, Industrial Safety and Health Act, Act for Securing the Proper Operation of Worker Dispatching Undertakings and Improved Working Conditions for Dispatched Workers (Worker Dispatch Law), Health Insurance Act, Workmen's Accident Compensation Insurance Act, Equal Employment Opportunity Law, etc.

3. We will comply with laws in all areas of our business activities and strive to maintain fair relationships with society.

(Explanation)

We will not only comply with laws and their spirit, but also act based on social norms and common sense in all business activities.
If we cannot rule out the possibility of violating these norms, we will stop the action.
We will strive to maintain a healthy relationship with healthcare professionals, and will not take any action that will amount to any suspicion of a cozy relationship.
We will strive to establish fair and transparent distribution and business practices in relation to business partners.
We will maintain a healthy relationship with politics, government, etc., and decisively confront antisocial forces and organizations that threaten the order and safety of society.

<Compliance program-related items for this provision>

(1) Relationship with Public Servants, etc.

(1) We will not provide, apply for, or promise illegal money, goods, etc., to any public servant, deemed public servant[*1], or person designated by a special law[*2] (hereinafter collectively referred to as "public servants, etc."). Even if we are asked to provide illegal money, goods, etc., we will decline it with a firm attitude.
(2) We will also not provide, apply for, or promise illegal money, goods, etc., to any foreign public servant, etc., in compliance with the laws and regulations of the country, the Unfair Competition Prevention Act, and Guidelines for the Prevention of Bribery of Foreign Public Officials of Japan, etc.

(Explanation/Supplement)

(1) The relationship with public servants, etc., is regulated by the Penal Code, National Public Service Ethics Act, Rules of Ethics for Government Officials, ethical rules of local governments and special corporations, etc. Acts such as providing illegal money, goods, etc., to public servants, etc., will be penalized. Such penalties are not only imposed on public servants, etc., who received these illegal items, but also on those who have provided them. Therefore, these acts must not be done.
Bribing Japanese public servants, etc., may be punished by laws and regulations of a third country as “bribery to foreign government officials, etc.,” from the perspective of the third country in some cases.
(2) Corruption, such as bribery, must not be engaged in even for foreign public servants, etc. A criminal punishment is imposed for providing unfair profits by the Unfair Competition Prevention Act in Japan, regardless of the place of conduct, in addition to the applicable laws and regulations related to corruption in the relevant country and the third country. In addition, the US Foreign Corrupt Practices Act, the UK Bribery Act, etc., may be applied in addressing corruption that takes place outside of the country.

*1 "Deemed public servant" means a person who is not a public servant but is treated as equivalent to a public servant pursuant to the provisions of the special law for the application of the Penal Code or other penalties.
Example: Officers and employees of national university corporations, the Pharmaceuticals and Medical Devices Agency, etc.

*2 "Person designated by a special law" means a person to whom penalties for bribery stipulated in the special law are applied directly pursuant to the provisions of the special law.
Example: Officers and employees of NTT, NTT East Japan, NTT West Japan, JR Hokkaido, JR Shikoku, JR Kyushu, JR Freight, Japan Tobacco Inc., etc.

Reference laws and regulations: Penal Code, Unfair Competition Prevention Act, National Public Service Act, Local Public Service Act, National Public Service Ethics Act, Rules of Ethics for Government Officials, Act of National University Corporations, U.S. Foreign Corrupt Practices Act, UK Bribery Act, etc.

Reference external standards, etc.: Guidelines for the Prevention of Bribery of Foreign Public Officials (Ministry of Economy, Trade and Industry (METI)), Fair Competition Rules for Drugs (Fair Trade Council of the Ethical Drug Manufacturing Industry), etc.

(2) 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 the provisions addressing bribery under the Penal Code, Political Funds Control Act, etc.

(Explanation/Supplement)

(1) We will strive to create a transparent relationship with the government, eliminating actions that may raise suspicions of inappropriate relationships.

(2) We will comply with relevant laws and regulations regarding payments to political parties, politicians, political groups, etc., including the Penal Code (crime of bribery), Political Funds Control Act, etc., regardless of the purpose, such as donations and purchase of party tickets related to politicians, etc. Political contributions must also be reasonable, transparent, and fair to fulfill accountability.

For more details on relationships with foreign politicians and the government, see the page offering information on “Relationship with Public Servants, etc.”

Reference laws and regulations: Penal Code, Unfair Competition Prevention Act, National Public Service Act, Local Public Service Act, National Public Service Ethics Act, Rules of Ethics for Government Officials, Political Funds Control Act, Act on Punishment of Public Officials' Profiting by Exerting Influence., etc.

(3) Outsourcing to Healthcare Professionals

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 laws and regulations. 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.

(Explanation/Supplement)

Care must be taken to ensure that no unauthorized payments will be made in nominal terms of consultancy, manuscript fees, etc. We must strictly avoid ambiguous payments and consideration should be given to conflicts of interest when consulting, advising, or other activities are outsourced.

In particular, if the other party is a public servant, etc., the transfer of money and goods must comply not only with the Penal Code (crime of bribery) but also with the National Public Service Ethics Act and other ethical laws, regulations, and standards.
In addition, the transparency of the relationship with healthcare professionals, etc., must be ensured by disclosing information on the provision of funds to the healthcare professionals, etc., based on the Clinical Research Act and voluntary industry codes.

Reference laws and regulations: Penal Code, National Public Service Act, Local Public Service Act, National Public Service Ethics Act, Rules of Ethics for Government Officials, etc.

Reference external standards, etc.: Transparency Guidelines for the Relation between Corporate Activities and Medical Institutions (JPMA), COI Management Guidelines for Clinical Research (Japan Medical Association), Fair Competition Rules for Drugs (Fair Trade Council of the Ethical Drug Manufacturing Industry), IFPMA Code of Practice (IFPMA), etc.

(4) Donation

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 to repay the amount and without using them as a means to induce transactions.

(Explanation/Supplement)
Opaque donations and grants must be strictly avoided in the same way as unfair payments for which the purpose is covered up. Donations and grants are the provision of money, etc., to the other party in a unidirectional manner. The independence of the organization must be respected, and the return of the amount donated must not be expected. In addition, the transparency of the relationship with such organizations must be ensured by disclosing information on donations and grants to the organizations based on the Clinical Research Act and other voluntary industry codes. If donations or grants to medical institutions, universities, external organizations, etc., may be used to exempt the application of the Penal Code (crime of bribery), National Public Service Ethics Act, and other ethical regulations, the request must be rejected.

Reference laws and regulations: Penal Code, Act against Unjustifiable Premiums and Misleading Representations, etc.

Reference external standards, etc.: Transparency Guidelines for the Relation between Corporate Activities and Medical Institutions (JPMA), Fair Competition Rules for Drugs (Fair Trade Council of the Ethical Drug Manufacturing Industry), JPMA Code of Practice (JPMA), etc.

(5) Prohibition of Unfair Transactions

In relation to medical institutions, competitors, distributors, and suppliers, we will conduct fair transactions in accordance with the rules of the Antimonopoly Act, Fair Competition Rules for Drugs, Subcontract Act, etc.

(Explanation/Supplement)
We will conduct fair transactions in compliance with the Antimonopoly Act, Unfair Competition

Prevention Act, Act against Unjustifiable Premiums and Misleading Representations, Subcontract Act, Fair Competition Rules for Drugs, JPMA Code of Practice, internal rules, etc. In addition, sales and profits obtained from unfair activities must not be evaluated as achievements.

(1) Relationship with medical institutions, etc.

In the ethical drug industry, the Fair Competition Rules for Drugs has been prepared based on the Act against Unjustifiable Premiums and Misleading Representations and certified by the Fair Trade Commission and Secretary-General of the Consumer Affairs Agency. Internal rules are prepared based on the Fair Competition Rules for Drugs and the JPMA Code of Practice and it is prohibited to provide medical institutions with premiums that unduly solicit transactions.

(2) Relationship with competitors

Any officer or employee engaged in any business operation must not limit competition in the market by making an agreement with a competitor on the price, quantity, sales destination (market), etc., of products. This is prohibited by the Antimonopoly Act as an improper trade restriction (cartel). Topics that may unduly limit prices, sales conditions, and market competition must not be discussed at meetings held for business and academic purposes. If such matters are discussed, we must leave such meetings immediately.

(3) Relationship with distributors

The Antimonopoly Law prohibits the following: unfair transactions undertaken to bind prices that a distributor such as a wholesaler sells products to medical institutions and pharmacies (resale price), setting discriminative business conditions for a distributor without reasonable cause, soliciting a distributor with unreasonable profits in light of normal business practices, and giving unreasonable damages by using the preferred business position.

(4) Relationship with suppliers and subcontractors

A healthy relationship must be maintained with suppliers (procurement sources) related to raw materials, facilities, materials, printed matter such as product information summary (such as product brochures), etc., as a good partner. Unfair transactions, such as forced discounts, postponement of payment, etc., using a superior position must not be carried out. The Subcontract Act must be complied with while dealing with subcontractors defined in the act. It should be noted that not only manufacturing outsourcing but also outsourcing of services including the preparation of information deliverables, such as translated materials, draft of clinical study report, etc., and subcontracting of tests undertaken from group companies are subject to the Subcontract Act.

While giving gifts, entertainment, etc., all officers and employees must comply with related laws, regulations, notifications, etc., voluntary industry codes, and internal rules. Even if there are no specific provisions in related laws, regulations, notifications, etc., voluntary industry codes, and internal rules, it must be within the range that is not too generous or excessive in light of social norms.

Reference laws and regulations: Companies Act, Antimonopoly Act, Act against Unjustifiable Premiums and Misleading Representations, Act against Delay in Payment of Subcontract Proceeds, Etc. to Subcontractors, Penal Code, National Public Service Ethics Act, Rules of Ethics for Government Officials, Consumer Contract Act, etc.

Reference external standards, etc.: Fair Competition Rules for Drugs (Fair Trade Council of the Ethical Drug Manufacturing Industry), etc.

(6) Response to Antisocial Forces and Organizations

We will not have any relationship with antisocial forces that threaten the order or safety of society, such as a corporate racketeer, organized crime group, etc., and firmly confront them without bowing to their unjustified demands.

(Explanation/Supplement)
Antisocial forces such as corporate racketeers, organized crime groups, etc., have spread and oligopolized extensively, and have also become skilled and diversified by pretending to engage in legitimate economic activities, etc.
It is prohibited by law to provide money or other benefits to antisocial forces. This must not be done even if such conduct does not violate the law.
For this reason, while concluding a business contract, care must be taken toward the other party and its surrounding circumstances to prevent the business contract from promoting the activities of antisocial forces or from supporting their operations. It is necessary to take appropriate measures such as including a special provision in the contract, so that if the other party is found to fall under the category of antisocial forces after the conclusion of the contract, the contract can be terminated promptly, etc.
If any provision of money or other benefits are required by antisocial forces including terrorists, etc., it must be declined firmly and handled in cooperation with the police and other external professional organizations.

Reference laws and regulations: Companies Act, Penal Code, Act concerning Punishment of Physical Violence and Others, Act for the Prevention of Wrongful Acts by Members of Organized Crime Groups, Anti-Organized Crime Law, Act for Punishment of Organized Crimes, Control of Crime Proceeds and Other Matters, Law on Proscribing Stalking Behavior and Assisting Victims, Act on Punishment of Activities Relating to Child Prostitution and Child Pornography, and the Protection of Children, Narcotics and Psychotropics Control Act, Cannabis Control Act, Opium Act, Stimulants Control Act, etc.

Reference external standards, etc.: Securities Listing Regulations (Tokyo Stock Exchange), Law for Ensuring the Quality, Efficacy, and Safety of Drugs and Medical Devices (Pharmaceutical and Medical Device Act), Guideline for How Companies Prevent Damage from Anti-Social Forces (Agreed upon at a meeting of ministers responsible for anti-crime measures), etc.

(7) Prohibition of Provision for Illegal Purposes and Private Use of Company Funds and 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.

(Explanation/Supplement)
(1) The company assets must be used lawfully and properly for the business operations of the company.
Improper receipt of company expenses and mixing private and public matters, such as private eating, drinking, communication, etc., will not be permitted.
(2) Information systems and equipment are also important assets of the company and must be used

effectively only for the business operations of the company. For example, personal use of e-mail for non-business-related communications or access to websites on the Internet for non-business purposes is prohibited. Officers and employees are required to avoid mixing private and public matters and use the company assets in a reasonable manner.

Reference laws and regulations: Penal Code, Companies Act, etc.

(8) Internal Control

(1) We will accurately record our business activities in preparing, creating, and storing accounting records and documents for regulatory submissions.

(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 conservation of assets.

(3) We will not conduct any acts such as illegal accounting, creative accounting, etc., but comply with the tax law and pay taxes properly.

(Explanation/Supplement)

Accounting books must reflect business activities accurately and double bookkeeping and making false entries are not permitted. Making up data and creating false records for documents, such as securities reports, that are required to be prepared and stored as required by laws and regulations and documents that are to be submitted to public offices are not permitted. Creating and retaining documents that accurately record business activities have important implications in case of litigation. There are records that are required to be submitted in the lawsuit procedure, and it is important to be able to confirm "what the fact was" in the lawsuit to make decisions for the company.

The company shall establish an internal control system for the disclosure of corporate information, management control, and monitoring. For such purposes, we will organize and properly operate various rules, organizations, etc., to improve the credibility, profitability, and social status.

Reference laws and regulations: Companies Act, Ordinance for Enforcement of the Companies Act, Corporate Accounting Rules, Financial Instruments and Exchange Act, Cabinet Office Ordinance on Disclosure of Corporate Information, etc., Cabinet Office Ordinance on the System for Ensuring Appropriateness of Statements on Finance and Accounting and Other Information, Foreign Exchange and Foreign Trade Act, Regulation for Terminology, Forms and Preparation of Financial Statements, Regulation for Terminology, Forms and Preparation of Consolidated Financial Statements, General Act of National Taxes, National Tax Collection Act, Income Tax Act, Corporation Tax Act, Local Tax Act, Consumption Tax Act, Act on Special Measures concerning Taxation, Land Value Tax Act, Stamp Duty Act, Customs Act, Registration and License Tax Act, etc.

Reference external standards, etc.: Points to consider for disclosure of corporate accounting principles, corporate accounting standards, corporate contents, etc. (Company content disclosure guidelines), Points to consider for "Guidelines on the Regulations for Terminology, Forms, and Preparation of Financial Statements" (Guidelines for regulations of financial statements, etc.), Points to consider for "Guidelines on the Regulations for Terminology, Forms, and Preparation of Consolidated Financial Statements" (Guidelines for regulations of consolidated financial statements, etc.), Points to consider for "Cabinet Office Ordinance on the System for Ensuring Appropriateness of Statements on

Finance and Accounting and Other Information" (Guidelines for Ordinance on Internal Control) (Financial Services Agency), On the Setting of the Standards and Practice Standards for Management Assessment and Audit concerning Internal Control Over Financial Reporting (Council Opinions) (Business Accounting Deliberation Council), etc.

(9) Handling of Intellectual Property Rights and Compliance with Regulations for Service Invention

(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 and not infringe the intellectual property rights of not only our company but also of third parties.

(3) We will comply with the regulations on the service invention of employees (Service Invention Regulations) and promote R&D activities.

(Explanation/Supplement)

(1) Intellectual property rights (patent rights, utility model rights, design rights, trademark rights, copyrights, trade secrets, etc.) are very important in the development and manufacturing of pharmaceutical products, etc., and therefore, they must be used legally and appropriately.

(2) If it is suspected that we infringe or may infringe the intellectual property rights of any third party, we must contact the intellectual property department immediately. For the protection of confidential information including trade secrets, see the page on "Handling of Confidential Information and Respect for Confidential Information of Third Parties."

(3) For service inventions of employees, we must establish and comply with the regulations for service inventions pursuant to Article 35 of the Patent Act. Officers and employees must report all results obtained in their work (including inventions, ideas, literary works, and all others to be protected as intellectual property rights) to the company. Then, the results must be vested or protected as confidential information according to the decision of the company.

Reference laws and regulations: Patent Act, Utility Model Act, Design Act, Trademark Act, Copyright Act, Unfair Competition Prevention Act, Plant Variety Protection and Seed Act, etc.

(10) 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. Confidential information of third parties obtained before joining the company and through temporary transfer to other companies, etc., shall not be disclosed or used within the company.

(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 misappropriate confidential information of the company or other companies for self-interest or interests of third parties.

(Explanation/Supplement)

Officers and employees contact the company with various kinds of information, such as technical, customer, and management information, etc., and also create their own information through their respective business operations. Information accumulated this way by the company should be managed as confidential information, depending on its importance. In addition, the same degree of management is required for information that the company is obligated to maintain confidential under laws, regulations, and contracts. Officers and employees must not disclose confidential information both to people outside the company (business partner, family, etc.) and also to personnel of the company except those who need such information for business purposes. When an officer or employee retires from the company, the company's confidential information obtained while he/she was employed must be kept confidential even after retirement.

If an employee worked at other companies or organizations before joining the company, he/she must submit a written pledge to the company that the information of the third parties will not be disclosed or used within the company and comply with it.

Other companies' confidential information constitute important property of these companies in the same way as our company's confidential information is important for us. In the Unfair Competition Prevention Act, in addition to the stipulation of civil remedies, such as damage compensation, etc., it is indicated that criminal punishment is applied to uses and disclosures of trade secrets after improper acquisition, uses and disclosures of trade secret recording media after improper acquisition, and unauthorized uses and disclosures of trade secrets after proper acquisition. Officers and employees who have the opportunity to contact confidential information of other companies, organizations, etc., must take utmost care not to infringe the confidential information of other companies, etc. In addition, when the provision of confidential information of other companies is proposed, it must be confirmed whether the other party has the legitimate authority to hold and disclose such information. If the route of obtainment seems doubtful, such information must not be received. In addition, for those who work in other companies, etc., before joining the company (mid-career employee), it is necessary to pay attention so that confidential information of other companies, etc., will not be disclosed and used in the company, that is, so-called information contamination will not occur.

With the advancement of informatization, a lot of confidential information is stored as electronic information in the company as well. In general, in addition to the ease of copying and falsification of electronic information, media that can record large amounts of electronic information have been used widely in recent times. Officers and employees must recognize that both confidential information stored as electronic information and that described in documents are equally important and valuable, and must manage electronic information appropriately as well.

Confidential information of the company and other companies obtained in the course of business must not be used privately for the benefit of individuals or any third parties.

While disclosing or providing confidential information of the company and other companies to business partners, etc., it is necessary to adequately manage and supervise such business partners, etc., so that such confidential information will be handled appropriately.

Utmost care must be taken not to disclose or leak confidential information of the company and other companies while using social media, such as social networking services (SNS), blogs, electronic bulletin boards, etc., personally and also for malicious e-mails by a third party, etc. Even if information is not confidential, it is strictly prohibited to disclose any uncertain information related to the company without discretion.

Reference laws and regulations: Penal Code, Law for Ensuring the Quality, Efficacy, and Safety of

Drugs and Medical Devices (Pharmaceutical and Medical Device Act), Unfair Competition Prevention Act, Act concerning the Prohibition of Unauthorized Computer Access, etc.

(11) Protection of Personal Information

(1) We recognize the importance of the protection of personal information and will comply with laws, regulations, and standards related to the protection of personal information. 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.

(Explanation/Supplement)

Compliance systems for the protection of personal information must be established to implement an appropriate internal system, including the chief privacy officer, protection system for unauthorized access from outside, safety control measures (e.g., access control and measures to prevent bringing information out of the company for insiders), management system at the time of outsourcing, education/enlightenment for employees, etc., operations for handling complaints, etc.

Basic policies, guidelines, etc., have been published by governments, ministries, and agencies, industry organizations, etc., and must be complied with along with laws and regulations.

Following the enforcement of the revised Personal Information Protection Law, “Individual identification code,” in which the physical characteristics of a specific individual are converted to data, is also defined as personal information since May 30, 2017 onward. While obtaining “Personal information requiring consideration” that requires special consideration to prevent unfair discrimination or prejudice to an individual, such as race, philosophy, medical history, etc., it is obligatory to obtain the consent of the individual in principle, imposing stricter obligations based on the Personal Information Protection Law. Employees must thoroughly understand the contents of the revised Personal Information Protection Law and handle personal information appropriately.

Reference laws and regulations: Act on the Protection of Personal Information (Personal Information Protection Law), Act on the Use of Numbers to Identify Specific Individuals in Administrative Procedures (Number Law), Penal Code, Law for Ensuring the Quality, Efficacy, and Safety of Drugs and Medical Devices (Pharmaceutical and Medical Device Act), Unfair Competition Prevention Act, Act concerning the Prohibition of Unauthorized Computer Access, etc.

Reference external standards, etc.: Basic Policy on the Protection of Personal Information (cabinet decision), Guidelines Targeting Economic and Industrial Sectors Pertaining to the Act on the Protection of Personal Information (METI), Guidelines on the Protection of Personal Information in the Employment Management Area (MHLW), Guidelines on Measures to be Taken by Business Operator to Ensure Proper Handling of Personal Information in Employment Management (MHLW), Points to Consider for Handling of Personal Health Information in Employment Management (MHLW), Guidelines on Proper Handling of Personal Information in Health Insurance Associations, etc. (MHLW), Guidelines on Proper Handling of Personal Information in Pharmaceutical Industry

(FPMAJ), Guidelines on Proper Handling of Specific Personal Information (for business operators) (Specific Personal Information Protection Committee), etc.

(12) Insider Trading Regulations, etc.

(1) In compliance with the Insider Trading Regulations stipulated in the Financial Instruments and Exchange Act, when we learn about unpublicized important facts regarding business operations of the 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 it is published through a certain procedure.

In addition, officers must comply with the regulations on transactions of treasury stock by officers stipulated in the Financial Instruments and Exchange Act.

(2) 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.

(Explanation/Supplement)

(1) It is extremely unfair to sell securities, such as stocks, etc., while knowing important confidential information that may affect the stock prices if it is published for general investors who do not know such information. Therefore, it is regulated by the Financial Instruments and Exchange Act as an insider trading. In particular, strict regulations are imposed on the sale and purchase of treasury shares by officers.

(2) While selling and purchasing treasury shares, etc., officers and employees must apply for permission to sell and purchase treasury shares, etc., to the department in charge in advance in accordance with the Internal Information Management Rules to obtain permission.

(3) To prevent insider trading, internal information of the company, subsidiaries, business partners, etc., must be managed strictly. It is prohibited by the Financial Instruments and Exchange Act to convey internal information or to recommend transactions to third parties (including other officers/employees, family members, friends, etc.) to obtain profits from transactions or avoid losses even if officers or employees of the company do not conduct insider trading on their own. Further, the company's rules on internal information management prohibit communication and transaction recommendations that are unnecessary for business operations, including those with no purpose mentioned above.

Reference laws and regulations: Financial Instruments and Exchange Act, Cabinet Office Ordinance Regarding Regulations on Securities Transactions, etc.

Reference external standards, etc.: Securities Listing Regulations (Tokyo Stock Exchange), etc.

(13) Internal Whistle-blowing System

(1) If we find any violation or suspected violation of laws and regulations in Japan and overseas, voluntary industry codes, internal rules, etc., we will promptly report it to the company.

(2) While receiving inquiries, consultations, and internal reports on violations or suspected violations of domestic and overseas laws and regulations, voluntary industry codes, internal rules, etc., 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.

(Explanation/Supplement)
Recently, a series of corporate scandals that undermine the trust of consumers have been revealed, triggered by whistle-blowing from inside the company (so-called whistle-blower). For this reason, an act to protect whistle-blowers (Whistle-Blower Protection Act) was enforced in April 2006 to protect employees from disadvantageous treatment, such as dismissal, etc., when they report violations of laws and regulations by business operators, strengthen the compliance management of business operators, and contribute to a stable public life and healthy development of the social economy. However, in consideration of the fact that there have been cases where whistle-blowers were dismissed or treated unfavorably in companies because of whistle-blowing and lawsuits for the treatments were filed in such cases, the Guidelines for Business Operators Regarding the Establishment, Maintenance and Operation of Internal Reporting Systems Based on the Whistle-Blower Protection Act (hereinafter "Revised Guidelines") was announced in December 2016 to improve the effectiveness of the internal whistle-blowing system, including the thorough prohibition of unfavorable treatments for whistle-blowers, the clarification of roles to be accomplished by executive managers, etc., and to further promote the efforts of business operators for compliance management.
We are required to promptly report to the company upon finding any violation or suspected violation of laws, regulations, voluntary industry codes, internal rules, etc., by officers or employees of the company.
The company must establish and operate an internal system to protect the rights of whistle-blowers related to public interest and prevent any unfavorable treatment in accordance with the Whistle-Blower Protection Act and Revised Guidelines. In the event of any violation of laws, regulations, etc., the company must take appropriate corrective actions promptly.

Reference laws and regulations: Whistle-Blower Protection Act, Labor Standards Act, etc.

Reference external standards, etc.: Guidelines for Business Operators Regarding the Establishment, Maintenance and Operation of Internal Reporting Systems Based on the Whistle-Blower Protection Act (Consumer Affairs Agency), etc.

(14) Response to International Standards and Overseas Laws and Regulations and Contribution to Local Societies

(1) We will respect not only international rules and local laws and regulations, 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 local laws and regulations, as well as to respect local cultures and practices while conducting international business activities.

(Explanation/Supplement)
As the world is becoming increasingly borderless, the environment in which pharmaceutical companies are placed is no exception. Opportunities for overseas business activities, such as expansion to the global market, standardization of clinical study standards by ICH, etc., are increasing. The basic principle for conducting business activities in and outside Japan is fairness. It is necessary not only to comply with international rules such as treaties and local laws and regulations, but also to act upon an

understanding of the local cultures and practices, especially in case of activities outside Japan. However, malicious practices should be confronted decisively. With the intention of engaging in internationalization, we need to promote business activities together with regions both in Japan and overseas.
To ensure the fair provision of medical information, it is natural to follow local codes. If there is no code in the country, medical information activities must be conducted based on the IFPMA Code of Practice.
The same applies to domestic and overseas group companies, business partners, etc.

Reference external standards, etc.: Charter of Corporate Behavior (Japan Economic Federation), Fair Competition Code (concerning Restriction on Premium Offers in Ethical Pharmaceutical Drugs Marketing Industry) (Fair Competition Rules), Code of Practices for Pharmaceutical Industry (FPMAJ), JPMA Promotion Code for Prescription Drugs (JPMA), JPMA Code of Practice (JPMA), Transparency Guidelines for the Relation between Corporate Activities and Medical Institutions (JPMA), Guidelines on Collaboration with Patient Organizations (JPMA), Transparency Guidelines for Relationship between Corporate Activities and Patient Groups (JPMA), IFPMA Code of Practice for Ethical Promotion of Drugs (IFPMA), UN Global Compact (United Nations), ISO26000 (Guidance for Social Responsibility), etc.

4. We will strive to protect the global environment in all areas of our business activities.

(Explanation)
Protecting the invaluable global environment and giving it to our descendants are duties for those of us who are alive today. It is a basic requirement to comply with the environment-related laws and regulations, and we will strive to save our resources and environment while setting our own voluntary goals and action plans.

<Compliance program-related items for this provision>

(1) Environmental Conservation

We will conduct business activities in compliance with environment-related laws and regulations 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.

(Explanation/Supplement)
Environmental problems, such as global warming, ozone depletion, acid rain, etc., have significant impacts on people, nature, etc. In particular, we, life science companies are responsible for actively working on environmental conservation. We are required to understand the importance of environmental issues and act with awareness in all aspects of our business activities.
We will assess the environmental impact of all our activities from research and development to production and sales, and promote energy and resource saving, reduction of industrial waste, recycling activities, and manufacture of safe products in consideration of the environment.
Attention must be paid to the Soil Contamination Countermeasures Act while developing our old factory site, etc.

Reference laws and regulations: Environmental Basic Act, Basic Act on Biodiversity, Act for the Settlement of Environmental Pollution Disputes, Act on Compensation, etc. of Pollution-related Health Damage, Air Pollution Control Act, Water Quality Pollution Control Act, Noise Regulation Act, Vibration Regulation Act, Offensive Odor Control Act, Wastes Disposal and Public Cleansing Act, Act on the Promotion of Effective Utilization of Resources, Environmental Pollution Control Expense Sharing Act, Act for evaluation of effects on the environment, Act for the Punishment of Environmental Pollution Crimes relating to Human Health, Act for prevention of soil contamination in farmland, etc., Act for Protection of the Ozone Layer through Regulation of Designated Substances, etc., Nature Conservation Act, Act for the Prevention of Marine Pollution and Maritime Disasters, Act on the Promotion of Sorted Garbage Collection and Recycling of Containers and Packaging, Soil Contamination Countermeasures Act, Act on Special Measures concerning Countermeasures against Dioxins, Act on Promotion of Global Warming Countermeasures, Act on the Rational Use of Energy, Act on Rational Use and Appropriate Management of Fluorocarbons, Sewerage Service Act, Basic Act for the Promotion of the Recycling-Oriented Society, Act on Special Measures concerning the Proper Treatment of Polychlorinated Biphenyl Waste, Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc., Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof, Act for the Establishment of Pollution Prevention Systems in Specified Factories, Fire Service Act, High Pressure Gas Safety Act, Poisonous and Deleterious Substances Control Act, etc.

5. We will aim for transparent management and actively disclose information on business activities.

(Explanation)
The company exists with the support of many people including its shareholders.
We will strive to achieve our corporate objectives by managing and operating our assets properly and efficiently.
Appropriate disclosures of company information not only to shareholders but also to society to ensure transparency is an important aspect of corporate responsibility for seeking proper social judgment. We will disclose company information proactively.

<Compliance program-related items for this provision>

(1) 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 relevant laws, regulations, notifications, voluntary industry codes, and internal rules, but such communications shall not result in advertisements of ethical drugs for people other than healthcare professionals.

(Explanation/Supplement)

(1) While disclosing corporate information, we must make efforts not only to do it in a timely and appropriate manner, but also to do so as required by stakeholders in accordance with the Financial Instruments and Exchange Act, Timely Disclosure Rules of the Securities Exchange, and our related regulations. Further, inquiries must be handled in good faith and accurately. These inquiries shall be fed

back to corporate insiders as necessary.
(2) While providing information using websites or conducting digital communication using social media, etc., we must be aware that the company takes all responsibility for the contents and pay attention to the following points with partner companies, etc.
・ While providing educational information, we will comply with the Law for Ensuring the Quality, Efficacy, and Safety of Drugs and Medical Devices (Pharmaceutical and Medical Device Act), Code of Fair Practices in the Advertising of Drug and Related Product, other regulations, JPMA Code of Practice, and internal rules so as not to advertise ethical drugs to anyone other than healthcare professionals.
・ If the company plans or supports digital communication using social media, etc., we must responsibly check the contents, including those posted by a third party, whether or not inappropriate information such as off-label use of our drug products, etc., or slander or defamation of other companies' products, etc., is included. If information on adverse events is published, we will respond to it appropriately based on relevant laws, regulations, voluntary industry codes, and internal rules.

Reference laws and regulations: Penal Code, Antimonopoly Law, Act against Unjustifiable Premiums and Misleading Representations, Unfair Competition Prevention Act, etc.

Reference external standards, etc.: Good Advertisement Standards for Drugs, etc. (Notification from the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW), Fair Competition Rules for Drugs (Fair Trade Council of the Ethical Drug Manufacturing Industry), JPMA Code of Practice (JPMA), etc.

(2) Avoidance of Conflict of Interest and Prevention of Mixing Private and Public Matters
(1) We must avoid situations where the interests of the company may come in conflict with the personal interests of officers and employees. Even if such situations cannot be avoided, personal benefits must not be prioritized.
(2) We will make the relationship with suppliers, business partners, users, etc., fair and healthy. We will not receive, demand, or promise illegal or unfair provision of profits (money, goods, entertainment, benefits, etc.) with respect to job positions or authority.

(Explanation/Supplement)
(1) In situations where the interests of the company may conflict with the personal interests of officers and employees, there is a risk of arbitrary transactions even if it is not illegal under the Penal Code (embezzlement and breach of trust), Companies Act (transactions involving a conflict of interest and aggravated breach of trust), etc. In such cases, personal interests must not be unduly prioritized. Officers and employees must consider what is best for the company and the company must establish a system of managing such conflicts of interest.
(2) While dealing with companies that are owned or managed by officers, employees, or their relatives, fraud is likely to occur. Further, if a relative of an officer or employee works at a business partner’s or competitor’s business, the officer or employee should not be involved in the business activities related to such business partner or competitor.
(3) Personal sponsorship to business partners and competitors should be avoided, except when the company specifically approves it, stock investments to listed companies, etc., because it increases the risk of conflict of interest.

(4) Hiring, promotion, evaluation, relocation, salary increase, etc., must be handled fairly at all times and must not be handled in a particularly advantageous manner by virtue of being a relative of an officer or employee.
If there is a relative of an officer or employee in the company, the officer or employee should not have any authority related to the promotion, evaluation, transfer, salary increase, etc., in connection with their relative.
(5) In the event that a board member conducts a transaction in a category of business activities of the company on his/her behalf or on behalf of a third party, the board member must disclose the material facts of such transactions at the board of directors and obtain approval for it. In addition, if transactions involving some conflict of interest are carried out, such as receiving the company's assets, transferring personal assets to the company, receiving a loan of money from the company, conducting transactions with the company on his/her behalf or on behalf of a third party, the company guaranteeing the liability of a board member, etc., the board member must also be approved by the board of directors.
(6) Receiving rebates, offering money, giving gifts, or getting entertainment personally from business partners, etc., in relation to business operations may distort business decisions and is a conflict of interest. Therefore, officers and employees must not receive them except for gifts, etc., that must be received out of courtesy.
While receiving gifts, entertainment, etc., from wholesalers, all officers and employees must comply with internal rules.

Reference laws and regulations: Penal Code, Companies Act, etc.

(3) Relationship with Patient Groups

(1) We will have high ethical standards and respect the independence of patient groups in all collaborations with such groups. Efforts will be made 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.

(Explanation/Supplement)
Our mission is to contribute to the improvement of the health and welfare of people around the world and to the realization of a healthy and high-quality life through the continued research and development on and stable supply of innovative drugs.
The pharmaceutical industry should understand and respond to the needs and concerns of patients, and therefore opportunities for collaboration with patient groups are on the rise. On the premise that integrity is essential in collaborations with patient groups, we must comply with internal rules, etc., based on the "Guidelines for Collaboration with Patient Groups," which is a voluntary industry standard, respect the independence of the other party, and make efforts for the full mutual understanding of the purpose and contents of the collaboration.
On the other hand, in order to realize "patient-participated medical care," the ability of patient groups to speak and influence is increasing in the government and medical community.
When we provide financial support, labor, etc., to patient groups, it is important to obtain a broad understanding of the contribution of these activities to the activities and development of patient groups after ensuring the high ethical nature of such activities. For this reason, in order to clarify the fact that

we are involved, the purpose, contents, etc., of such activities must be clearly stated in writing in advance and records must be kept based on mutual agreement. Further, the information must be disclosed in compliance with internal rules, etc., based on the "Transparency Guidelines for Relationship between Corporate Activities and Patient Groups," which is a voluntary industry standard, to ensure the transparency of the relationship with patient groups.

Reference external standards, etc.: JPMA Code of Practice (JPMA), Guidelines on Collaboration with Patient Organizations (JPMA), Transparency Guidelines for Relationship between Corporate Activities and Patient Groups (JPMA), IFPMA Code of Practice (IFPMA), etc.

6. We will harmonize with society as a corporate citizen.

(Explanation)
The company is also required to play an active role as a good corporate citizen.
In addition to developing and providing excellent new drugs that help people by providing for their medical care and that contribute to society, we will continue to cooperate with society and play our role as a corporate citizen.

<Compliance program-related items for this provision>
(1) 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 employees' volunteer activities.

(Explanation/Supplement)
As people engaged in a life science company handling products related to human health, we will act not only in compliance with laws and regulations, but also with high ethical standards including life ethics. Then, with a long-term perspective, we will strive to promote business activities based on mutual trust with stakeholders around us. For this purpose, in each country or region where our business activities are conducted, we will communicate our interests and intentions to stakeholders to seek their understanding, to understand local social circumstances, and to conduct activities with due consideration for their cultures, customs, and religions.
We will have a wide range of interests and understand the trends in social issues, including those faced by local and international communities and new issues arising from economic and social changes on a regular basis. We will also select areas to be addressed through social contribution activities, while taking our management philosophy, business contents, management resources, etc., into account in order to promote them. For this approach, we will consider developing human resources who support the realization of a sustainable society.
The methods of social contribution include the provision of various resources such as donations, voluntary programs, cooperation and collaboration with NPOs, NGOs, etc., support for social participation of employees, and cooperation with corporate foundations, etc. We will combine these

methods as appropriate to implement them.
It is important that we work with partners such as NPOs, NGOs, community volunteer groups, governments, and public sector establishments, etc., to address social challenges. This allows us to mutually complement resources, know-how, and information, thereby allowing us to perform extensive activities within a short period of time. By cooperating with these partners, we can quickly learn the opinions of those at the grass roots and the reality, trends, and reactions of society that are difficult to understand from our standpoint. This will increase our speed and efficiency in solving problems and enable us to engage in more effective social contribution activities.
We will remain committed to improving the environment and creating opportunities for the social participation of employees while respecting individual autonomy in order to maximize the effectiveness of support. We will also support the construction of a rich second life for retirees through social contribution activities.

Reference laws and regulations: Labor Standards Act, etc.

Reference external standards, etc.: UN Volunteer Program (United Nations), Universal Declaration on Volunteering (International Association for Volunteer Effort (IAVE)), JPMA Code of Practice (JPMA), etc.