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■ Fundamental Principles

1. Fundamental Principles

[1] We will act in compliance with Applicable Laws and Regulations and uphold the highest ethical standards, including bioethics, as members of a life-science company whose products directly affect human health.

[2] We will prioritize actions grounded in strong ethical values over the pursuit of corporate profit or individual achievement, and we will not allow ourselves to be driven solely by business motives.

[3] We will recognize that we retain final responsibility across all stages of research, development, manufacturing, and sales, even when certain tasks are outsourced. We will communicate the intent and principles of these Guidelines to contractors and will work with them in a unified and responsible manner.

■ Compliance in Business Activities

2. Drug Discovery Research

[1] We will confirm, at all times throughout the drug discovery process, whether substances synthesized internally or obtained from external sources fall under regulated categories, such as poisonous or deleterious substances, radioactive materials, narcotics, psychotropic drugs, or stimulant drugs, under Applicable Laws and Regulations, and we will take appropriate actions in accordance with such laws.

[2] We will comply with all Applicable Laws and Regulations as well as All Policies, Manuals and GxP-SOPs when using genes or human-derived tissues and will implement all necessary measures to ensure the protection of personal information related to such tissues. Furthermore, in conducting genetic modification experiments, we will strictly comply with legal requirements and enforce rigorous safety management to prevent genetically modified organisms from affecting wild fauna and flora.

[3] We will comply with Applicable Laws and Regulations and will take all necessary measures to prevent biohazard incidents caused by pathogens.

[4] When conducting animal studies, we will comply with Applicable Laws and Regulations as well as All Policies, Manuals and GxP-SOPs, respect the lives of animals, limit animal use to the minimum necessary, make every effort to avoid causing pain or distress, and consider the development and adoption of alternative methods.

3. Clinical Trial

[1] We will conduct clinical trials in full compliance with Applicable Laws and Regulations, All Policies, Manuals, and GxP-SOPs. Furthermore, based on data obtained through our research and development activities, we will thoroughly assess whether the investigational

product possesses adequate scientific value and justification for conducting the clinical trial.

[2] We will respect the rights and dignity of clinical trial participants to the greatest extent possible. We will provide medical institutions with all necessary information in an appropriate and timely manner, and if we determine that any safety concern exists, we will immediately review the study plan and make an appropriate judgment regarding the continuation or suspension of the clinical trial.

In addition, we will ensure that adequate measures are in place to prepare for any potential health injury to participants in all clinical trials we conduct.

[3] We will prepare objective, accurate, and verifiable data concerning the efficacy and safety of investigational products, and we will not engage in any form of data falsification, concealment, or other misconduct. We will also refrain from requesting or encouraging any such improper practices from contractors or joint research institutions.

[4] We will disclose clinical trial information and information regarding expenses incurred in the conduct of clinical trials in a lawful, appropriate, and transparent manner, in accordance with Applicable Laws and Regulations.

4. Application for Approval

[1] We will, when submitting applications for marketing authorization of pharmaceuticals—including applications for partial changes and notifications of minor changes—prepare application materials accurately based on the results obtained from surveys or tests conducted in compliance with Applicable Laws and Regulations, All Policies, Manuals, and GxP-SOPs.

[2] We will, when obtaining survey results including those from post-marketing surveillance, study findings, or other data that may cast doubt on the quality, efficacy, or safety of the pharmaceutical product subject to the application, examine and evaluate such information appropriately and include the results in the application materials. We will not engage in any improper acts such as falsification, replacement, or concealment of data.

[3] We will, when such studies or tests are conducted by Subsidiaries or contractors, provide sufficient supervision over their implementation and ensure that the conduct of the studies or tests and the acquisition of data are carried out appropriately.

5. Post-marketing Safety Management, Surveillance

[1] We will conduct post-marketing safety management activities and post-marketing surveillance in compliance with Applicable Laws and Regulations, All Policies, Manuals, and GxP-SOPs, in order to ensure the proper use of pharmaceuticals after marketing authorization.

[2] We will promptly report any suspected adverse events caused by our products to the relevant authorities in accordance with Applicable Laws and Regulations, All Policies, Manuals,

and GxP-SOPs, and we will take appropriate safety measures as necessary.

[3] We will conduct, as applicable, post-marketing surveillance in compliance with Applicable Laws and Regulations, All Policies, Manuals, and GxP-SOPs for the purpose of collecting and preparing data required for re-examination, re-evaluation, and other pharmacovigilance activities.

6. Clinical Research

[1] We will support clinical research in compliance with Applicable Laws and Regulations, and we will thoroughly assess—based on data obtained through research and development—whether such support has sufficient scientific value and justification.

[2] We will give due consideration to conflicts of interest, disclose information on funding, and enhance transparency in accordance with Applicable Laws and Regulations.

7. Supply Chain

[1] We will recognize the importance of our products for human life and will ensure that our products are supplied to medical institutions and patients in a stable and timely manner.

[2] We will comply with Applicable Laws and Regulations, All Policies, Manuals, and GxP-SOPs in the manufacturing of our products, including processes performed by contract manufacturers. We will maintain appropriate manufacturing and quality control throughout the entire manufacturing process and make every effort to ensure safe operations that prevent accidents or disasters. If any issue arises concerning the manufacturing or quality of a pharmaceutical product, we will take appropriate measures with the highest priority on human life and will promptly investigate the cause and implement measures to prevent recurrence.

[3] We will conduct the logistics and import/export of raw materials, products, facilities, equipment, software, and other relevant items appropriately and in compliance with Applicable Laws and Regulations, All Policies, Manuals, and GxP-SOPs.

[4] We will handle raw materials used in the manufacture of products in compliance with Applicable Laws and Regulations, All Policies, Manuals, and GxP-SOPs, and we will take appropriate measures with due consideration for the health of Employees involved in manufacturing processes and for the impact on the environment resulting from external discharge.

■ Relationship with Stakeholders

8. Interactions with Healthcare Professionals (Including Medical Information Activities)

[1] We will engage in interactions with healthcare professionals—including medical information activities for medical institutions—in a fair and transparent manner, in compliance with Applicable Laws and Regulations, All Policies, Manuals, and GxP-SOPs.

[2] We will acquire the medical and pharmaceutical knowledge necessary for interacting with healthcare professionals and will provide information on pharmaceuticals accurately and appropriately to contribute to the health of patients and the general public, in accordance with Applicable Laws and Regulations.

[3] We will provide information on our products to healthcare professionals only within the scope of their approved manufacturing and marketing authorization.

[4] We will maintain sound and appropriate relationships with physicians, pharmacists, and other healthcare professionals at medical institutions that are regarded as public servants or deemed equivalent, so as not to violate or be suspected of violating Applicable Laws and Regulations.

9. Corporate Communication Activities

[1] We will disclose corporate information required by society in a timely and appropriate manner, listen to stakeholders' perspectives, and engage in constructive communication with society.

[2] We will provide information through websites and manage digital communications, including the use of social media, in compliance with and as permitted by Applicable Laws and Regulations, All Policies, Manuals, and GxP-SOPs.

10. Contribution to Society and Sustainable Development

[1] We will engage with local communities by respecting their culture, religion, traditions, and social characteristics, and we will build mutual trust with our stakeholders through these activities as permissible.

[2] We will identify priority social issues and the management resources that the Ono Group can contribute, in alignment with our corporate philosophy, when promoting social contribution activities.

[3] We will collaborate with a wide range of stakeholders—including NPOs/NGOs, local communities, and government agencies—to contribute to social development and sustainability as permissible.

[4] We will support volunteer activities by Employees.

11. Relationship with Patient Groups

[1] We will act with high ethical standards and integrity in all collaborations with patient organizations and in strict compliance with Applicable Laws and Regulations, and we will respect the independence of each patient group. We will make every effort to ensure mutual understanding of the objectives and scope of our collaborations.

[2] We will enhance transparency and public trust by appropriately disclosing financial

and other support provided to patient groups, ensuring that such support meaningfully contributes to their activities and development.

12. Relationship with Public Officials

We will not offer, promise, or provide any illegal money, goods, or other benefits to public officials or individuals treated as public officials, and we will firmly refuse any improper requests.

13. Relationship with Politics and the Administrative Bodies

[1] We will build appropriate and transparent relationships with political and administrative bodies.

[2] We will ensure that any payments or contributions made to political parties, politicians, or political organizations are legitimate, transparent, and compliant with Applicable Laws and Regulations, regardless of their stated purpose.

14. Commissioning Work to Healthcare Professionals and Other Experts

We will ensure that any engagement of healthcare professionals or other experts, including consultants and advisors, complies with Applicable Laws and Regulations, and we will always enter into a written contract. We will ensure that fees such as consulting or advisory fees appropriately reflect the value of the services provided, and we will document the content of those services in writing. We will comply with any policies or procedures established by the organization to which the counterpart belongs regarding consultancy or advisory activities.

15. Donations and Grants

We will ensure that any donations or grants respectively made to medical institutions, universities, or external organizations are lawful and provided solely as genuine donations or grants. We will not request any return benefit, nor will we use donations or grants to improperly induce transactions.

16. Sponsorship and Support for Scientific or Professional Events

We will ensure that any sponsorship provided for symposiums, academic meetings, scientific or professional events involving healthcare professionals or patient organizations has an appropriate purpose and is conducted in compliance with Applicable Laws and Regulations.

■ Fair Business Activities and Governance

17. Environmental Conservation

We will conduct our business activities in compliance with Applicable Laws and Regulations related to the environment, and we will consistently give due consideration to the impact of our

activities on the global environment as well as on the environments of local communities, as a life-science company.

18. Prohibition of Unfair Transactions

We will conduct fair transactions with medical institutions, competitors, customers, and suppliers in accordance with Applicable Laws and Regulations.

19. Management of Conflict of Interest

[1] We will avoid any situation in which the interests of the company may conflict with the personal interests of Employees.

We will not prioritize personal interests even when such situations cannot be avoided.

[2] We will maintain fair and sound relationships with suppliers, business partners, customers, and other stakeholders, and we will not receive or request illegal or improper benefits, including money, goods, entertainment, or other advantages, in connection with our duties or authority.

20. Response to Anti-social Forces

We will not have any relationship with antisocial forces that threaten social order or safety, and we will firmly reject and confront any improper demands made by such groups.

21. Human Rights

[1] We will understand and respect human rights as well as the diverse values, personalities, and individuality of others. We will also express our commitment to respecting human rights within our supply chain and seek understanding from our business partners.

22. Prohibition of Discrimination, Harassment and Other Inappropriate Conduct

[1] We will not engage in any form of discrimination, harassment, or other inappropriate conduct based on race, nationality, ethnicity, gender, age, religion, beliefs, sexual orientation, gender expression, gender identity, educational background, disability, medical condition, or any other personal attributes, including in employment, treatment, or promotion decisions.

[2] We will respect the dignity of all individuals in the workplace and will not tolerate any form of harassment in the workplace, ensuring a work environment that is comfortable and conducive to productive work.

23. Workplace Environment

We will comply with labor-related Applicable Laws and Regulations. We will create a safe, healthy, and supportive workplace environment, and we will work to prevent occupational

accidents and maintain the health of Employees.

24. Fair Human Resource Practices

We will comply with Applicable Laws and Regulations and with All Policies, Manuals and GxP-SOPs, and we will promote appropriate placement and mobility of Employees while ensuring fair personnel evaluations. We will not grant preferential treatment in personnel assignments, evaluations, or promotions based on personal relationships, including family or other close relationships.

25. Internal Control

[1] We will maintain accurate records of our business activities when preparing, creating, and retaining accounting records and documents submitted to government authorities.

[2] We will establish and operate internal controls to ensure operational effectiveness and efficiency, reliability of financial reporting, compliance with Applicable Laws and Regulations, and protection of assets.

[3] We will not engage in improper accounting or falsification of financial statements, and we will comply with Applicable Laws and Regulations and pay taxes appropriately.

26. Whistleblowing

[1] We will promptly report any violations or suspected violations of Applicable Laws and Regulations, All Policies, Manuals and GxP-SOPs.

[2] We will appropriately respond to inquiries, consultations, or whistleblowing reports regarding violations or suspected violations, and we will not treat anyone unfavorably for making such inquiries, consultations, or reports.

[3] We will respond sincerely to whistleblowing reports or related inquiries or consultations from former Employees or business partners.

27. International Standards, Overseas Legal Compliance, and Contribution to Local Communities

We will comply with international rules and local Applicable Laws and Regulations in our global business activities, and we will respect the culture and customs of the regions in which we operate.

■ Management of Information and Assets

28. Prohibition of Personal Use of Company Assets

We will use company funds, property, and other assets solely for legitimate business purposes and will not use them for personal benefit or for the benefit of any third party.

29. Intellectual Property Rights and Compliance with Service Invention Rules

[1] We will recognize the importance of intellectual property rights and will make appropriate and lawful use of the results of our research and development activities.

[2] We will respect the intellectual property rights of third parties in the same manner as our own and will not infringe upon them.

[3] We will comply with the rules governing service inventions by Employees and will promote research and development activities in accordance with those rules.

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

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

[2] We will respect the confidential information of third parties, including companies and other organizations, and will not improperly acquire, use, or disclose such information. We will not disclose or use for company purposes any third-party confidential information learned prior to employment or through temporary assignments.

[3] We will recognize that confidential information stored electronically has the same value as information in written form and will manage it appropriately.

[4] We will not misuse confidential information of the company or of third parties for our own benefit or for the benefit of any third party.

31. Protection of Personal Information

[1] We will recognize the importance of protecting personal information and will comply with Applicable Laws and Regulations and relevant standards. We will establish and operate an appropriate compliance framework to promote the protection of personal information and prevent its unauthorized disclosure.

[2] We will take necessary and appropriate measures for the protection of personal information, including proper acquisition, notification or publication of the purpose of use, prohibition of use beyond the stated purpose, implementation of security controls, education of Employees, restrictions on disclosure to third parties, and procedures to respond to requests for the disclosure of retained personal data.

32. Insider Trading Regulations

[1] We will comply with insider trading regulations under Applicable Laws and Regulations, and we will not trade the securities of OPJP, Subsidiaries, business partners, or any other related companies based on undisclosed material information learned through our duties until that information has been properly disclosed. We will ensure that directors or

corporate officers comply with the regulations governing directors or corporate officers' trading of our own company's securities.

[2] We will strictly manage any undisclosed material information learned through our duties and will not disclose such information or recommend transactions to third parties unless required for legitimate business purposes.