Sumitomo Pharma Co., Ltd

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Compliance Standard

1. Basic Concept

(1) As a company engaged in the life science industry that requires high ethical standards, we shall comply with laws and regulations, and conduct transparent and fair corporate activities with a strong commitment to ethical behavior.

(2) We shall act with the acknowledgement that the implementation of compliance is a major prerequisite for the continued existence of companies. Should any event occur that is against the spirit of compliance, we shall endeavor to identify the root cause and prevent the recurrence thereof, and also take strict and fair measures.

(3) We shall endeavor to handle transactions based on healthy, fair and equal partnerships with business partners, acknowledging that, even if we outsource business to them, we will be ultimately held accountable for the relevant products and services.

(4) We shall observe international rules and local laws and regulations in our cross-border business activities, and shall respect local culture and customs.

(5) We shall require and request our subsidiaries and affiliates or the like in and outside Japan to comply with applicable laws and regulations and corporate ethics.

2. Prevention of Misconduct Relating to Research Activities

(1) We shall conduct our research activities with pride and with a strong commitment to ethics. As a principle, we shall create new knowledge based on the accumulation of the search for truth, and shall not commit any misconduct.

(2) We shall be mindful of the fact that research activities are based on credibility by the public. We shall conduct our research activities fairly and honestly in compliance with applicable laws and regulations as well as internal rules.

(3) In order to secure the credibility of research results, we shall properly record our research activities and shall properly keep such records together with research results that were obtained.

(4) When we release our research results, we shall present objective and verifiable data and materials based on experiments implemented with methods which ensure scientific quality.

(5) We shall properly manage and use public research funds when they are provided to us.

(6) We shall clarify the framework of responsibility to take measures against misconduct

relating to research activities and shall make efforts to prevent such misconduct.

3. Drug Discovery Research

(1) With respect to materials that we synthesize during the process of the drug discovery research or obtain from outside of the Company, regardless of whether they are new materials or in the public domain, we shall confirm in advance whether or not such materials are regulated under laws and regulations (such as radioactive materials, narcotics, stimulants, raw materials of stimulants, psychotropic substances, poisonous and deleterious substances), and shall conduct research in accordance with applicable laws and regulations.

(2) When we conduct genetic recombination experiments, we shall comply with laws and regulations, and thoroughly ensure the management of safety so that gene-modified organisms or the like will not impact wild fauna and flora or the like.

(3) When we conduct research that involves human specimens (including human iPS cells, and excluding human ES cells), we shall comply with applicable ethical guidelines and shall be considerate of the human rights of those who provide samples.

(4) When we conduct research that involves human ES cells, we shall comply with the applicable ethical guidelines, and shall be fully considerate of the human rights of the donors, while taking into consideration that such research involves bioethical issues, including the fact that human ES cells are a derivative of destroyed human embryos, which are the beginning of human life, and have the potential to differentiate into any type of human cells.

(5) We shall comply with the Act on Prevention of Infectious Diseases and Medical Care for Patients Suffering Infectious Diseases, the Act on Domestic Animal Infectious Diseases Control, and the like and prevent biohazard accidents caused by pathogens or the like.

4. Non-Clinical Studies

(1) When we conduct non-clinical studies, we shall comply with applicable laws and regulations as well as internal rules, and generate accurate data that will allow the making of proper decisions regarding efficacy, safety or the like.

(2) When we conduct animal tests, we shall follow applicable laws and regulations as well as internal rules, and exert efforts to achieve the 3Rs (Replacement: to use alternative non-animal methods, Reduction: to reduce the number of animals used for animal tests, and Refinement: to alleviate pain, suffering or distress). We shall have an inspection conducted by a third party and receive a certification on our compliance therewith.

5. Clinical Trials

(1) When we conduct clinical trials, we shall comply with applicable laws and regulations as well as internal rules. We shall sufficiently investigate whether the drugs deserves to have clinical trials conducted based on the data that was obtained through research and development.

(2) When we conduct clinical trials, we shall give utmost respect to the human rights of the subjects. We shall adequately provide the necessary information to the medical institutions, and should we become aware of any safety issue or determine that the relevant drug has no efficacy, we will immediately revise the relevant trial plan and appropriately determine whether or not to continue the trial. Furthermore, we shall be prepared for any occurrence of health damages to the subjects in all clinical trials that we conduct.

(3) When we conduct clinical trials, we shall generate objective and accurate data regarding efficacy, safety or the like of drugs or the like, and shall never be involved in fraudulent acts including falsification or concealment of data. We shall not demand any of our contractors, collaborating research organizations or the like to be involved in such fraudulent acts.

(4) When we request medical institutions to conduct clinical trials, we shall conclude a written contract. We shall clarify the method of payment of expenses to medical institutions, and shall not make any payment under the name of a scholarship contribution, manuscript fees or the like, which is different from the actual service.(5) We shall appropriately disclose information regarding clinical trials and the costs that occur in conducting clinical trials in accordance with the industry self-regulations and thereby improve the transparency of the same.

(6) In our relationship with physicians or the like who are working for public medical institutions where we request the conduct of clinical trials, we shall maintain a healthy relationship with them so as not to violate or be suspected of violating the Penal Code (crime of bribery), the National Public Service Ethics Act, and other applicable laws and regulations.

6. Application for Approval

When we apply for the manufacturing and marketing approval (including applications for partial changes and/or the filing of minor change notice), we shall comply with applicable laws and regulations as well as internal rules, and only use application materials that accurately describe data and facts based on studies that were conducted ensuring the scientific quality and credibility of the results. We shall never use data obtained from studies conducted in a manner that deviated from applicable laws and regulations or internal rules, nor shall we ever be involved in fraudulent acts including falsification, replacement or concealment of data. When we outsource such studies to outsourcing contractors, we shall sufficiently manage and supervise those outsourcing contractors to ensure that the studies

and obtainment of data are carried out properly.

7. Post-Marketing Safety Management and Post-Marketing Surveillance

(1) In order to ensure the safety of drugs or the like after manufacturing and marketing and to establish the proper use thereof, we shall conduct post-marketing safety management operations and post-marketing surveillance in compliance with applicable laws and regulations as well as internal rules.

(2) When there is any suspicion that an adverse event has occurred due to any of our products, we shall promptly evaluate such suspicion, promptly report to the relevant authority in compliance with applicable laws and regulations as well as internal rules, and take appropriate measures to ensure the safety as necessary.

(3) We shall conduct surveys and studies in compliance with applicable laws and regulations as well as internal rules, to collect and create re-examination or re-evaluation materials, and also as a part of activities to monitor the safety of drugs or the like.

8. Clinical Research

(1) When we support or conduct clinical research, we shall comply with applicable laws and regulations including the Clinical Trials Act, the Ethical Guidelines for Life Science / Medical and Health Research Involving Human Subjects, the Fair Competition Code Concerning Restriction on Premium Offers in the Ethical Pharmaceutical Drugs Marketing Industry (hereinafter referred to as the “Fair Competition Code”) as well as the industry self-regulations and internal rules. We shall sufficiently investigate whether it is worthwhile for the Company to support and conduct such clinical research based on the data that was obtained through research and development.

(2) When we support or conduct clinical research, we shall give utmost respect to the human rights of the subjects. We shall adequately provide the necessary information to the medical institutions, and should we become aware of any safety issue or determine that the relevant drug has no efficacy, we will immediately revise the relevant research plan and appropriately determine whether or not to continue the research. Furthermore, we shall be prepared for any occurrence of health damages to the subjects in clinical research that we conduct.

(3) When we conduct clinical research, we shall generate objective and accurate data regarding efficacy, safety or the like of drugs or the like, and shall never be involved in fraudulent acts including falsification or concealment of data.

(4) When we support or conduct clinical research, we shall conclude a written contract with researchers, medical institutions and others pursuant to the Clinical Trial Act and other applicable laws and regulations to clarify each party’s responsibility. We shall pay attention to any conflict of interests in accordance with the Clinical Trial Act, industry self-regulations and other applicable laws and regulations, and appropriately disclose information regarding our provision of funds and thereby improve the transparency of the

same.

(5) When we support or conduct clinical research, we shall maintain a healthy relationship with physicians or the like who are working for public medical institutions so as not to violate or be suspected of violating the Penal Code (crime of bribery), the National Public Service Ethics Act, and other applicable laws and regulations.

9. Manufacturing

(1) We shall be aware of the fact that our products are related to people's lives, and ensure the stable supply of products to patients through medical institutions in a timely and appropriate manner.

(2) We shall observe applicable laws and regulations as well as internal rules in manufacturing products and investigational new drugs, and fully implement manufacturing and quality control measures through the entire process of manufacturing, including the processes at the contract manufacturers. Should any problem arise with respect to product quality, we shall promptly take appropriate measures, including product recovery, placing the first priority on the prevention of health damages. In addition, we shall identify the root cause and take necessary measures to prevent recurrences.

(3) In running plants and manufacturing equipment, we shall observe applicable laws and regulations as well as internal rules and take appropriate measures in order to prevent accidents and disasters, including fires and explosions and to ensure the safety of the employees and local community. Should any accident or disaster including a fire and explosion occur, we shall take measures that give top priority to human life, and make efforts to identify the root cause and prevent recurrences.

(4) When we handle chemical substances such as raw materials used for manufacturing products, we shall observe applicable laws and regulations as well as internal rules and take appropriate measures, taking into account the effects on the health of employees during the manufacturing process and the environmental impact due to external emissions.

10. Logistics, Import and Export

We shall observe applicable laws and regulations as well as internal rules in relation to logistics, import and export of products, raw materials, equipment, devices, software or the like, and appropriately carry out such logistics, import and export operations

11. Protection of the Environment

We shall observe environment-related laws and regulations as well as internal rules, and always conduct business activities in a manner that is considerate of the effects on the global environment and the environment of local communities.

12. Cooperation with Healthcare Professionals, etc.

(1) When we cooperate with healthcare professionals or the like, we shall comply with applicable laws and regulations, the Guidelines for Provision of Sales Information on Prescription Drugs, the Fair Competition Code, the JPMA Code of Practice, the IFPMA Code of Practice, internal rules and the like to ensure fair and transparent activities.

(2) We shall learn the medical and pharmaceutical knowledge necessary for cooperation with healthcare professionals or the like, and provide proper information to promote the proper use of drugs or the like in accordance with applicable laws and regulations such as the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices.

(3) We shall observe applicable laws and regulations as well as corporate ethics to appropriately conduct advertising activities. We shall ensure fairness in the contents and expressions of advertising activities so that such activities are not regarded as false or exaggerated advertisement nor will it constitute social discrimination or violation of the human rights.

(4) We shall maintain a healthy relationship in our cooperation with healthcare professionals or the like who are working for public medical institutions so as not to violate, or be suspected of violating, the Penal Code (crime of bribery), the National Public Service Ethics Act and other applicable laws and regulations.

13. Sales, Marketing and Information Communication Activities

In the sale and marketing of, and information communication for our products, we shall conduct fair sales activities in accordance with applicable laws and regulations and corporate ethics.

14. Corporate Communication Activities

(1) We shall disclose the information that society needs in a timely, appropriate and fair manner and also listen to the expectations and requests from society, and thereby facilitate communication with society.

(2) We shall conduct public relations activities in accordance with applicable laws and regulations, and provide shareholders and investors, employees, patients and their families, healthcare professionals and others with information that meets their respective needs in an easy-to-understand manner, putting ourselves in their respective positions.

15. Digital Communications Utilizing Social Media, etc.

We shall observe applicable laws and regulations as well as internal rules in making digital communications utilizing social media, websites or the like.

16. Relationship with Patient Organizations

(1) Whenever we collaborate with patient organizations, we shall have a strong

commitment to ethical behavior, and respect the independence of patient organizations. We shall make efforts to have a sufficient mutual understanding regarding the purpose and contents of the collaboration with patient organizations.

(2) We shall ensure transparency and make efforts to improve the credibility of our financial support or the like provided in our collaboration with patient organizations so that our contribution to the activities and development of patient organizations will be widely understood.

17. Prohibition of the Provision of Unjust Profit to Government Officials

(1) We shall not provide, offer or promise to provide, unjust profit (money, goods, etc.) to government officials, deemed government officials or any individual designated under special laws (hereinafter collectively referred to as “Government Officials”). Furthermore, we shall firmly refuse a request to provide unjust profit.

(2) We shall not provide, offer or promise to provide, unjust profit to Government Officials of foreign countries in compliance with applicable domestic and foreign corrupt practices laws and regulations.

18. Relationship with the Government and Administration

(1) We shall exert efforts to build a healthy and transparent relationship with the government and administration.

(2) We shall not make any unjust monetary payment or other similar payment to political parties, politicians, political organizations or the like, regardless of the name under which such payment is made.

19. Request for Consultation and Other Services

When we ask healthcare professionals and other experts for consultation, advisory or other services, we shall comply with applicable laws and regulations and always conclude a written contract. The amount of consideration must be appropriate for the services that we receive, and the details of the services must be recorded in writing. If the organization where the service provider belongs has its own internal rules on consultation, advisory or other services, we shall also observe such internal rules.

20. Contribution

When we make contributions to medical institutions, universities and other external organizations, we shall confirm that our contributions are not illegal. We shall make contributions based on a pure intent without requesting any trade-offs from the recipient, and shall not use contributions as a means to unjustly induce business from the recipient.

21. Prohibition of Unfair Trade Practices

(1) In our relationship with medical institutions, competitors, business partners and others,

we shall follow the rules set by the Antimonopoly Act, Subcontract Act, Fair Competition Code and other regulations, to ensure fair, legitimate and transparent corporate activities.

(2) In our business activities, including in promotional activities and sales activities, we shall not give illegal or unjust gifts, entertainment, rebates or the like to healthcare professionals, persons in charge of relevant dealings at our business partners, university staff, researchers, medical institutions, wholesalers and patient organizations.

22. Management of Conflict of Interest

(1) We shall avoid any situation where the Company's interests conflict with personal interests of officers or employees, and if such situation seems unavoidable, we shall properly handle the situation so that personal interests will not be unfairly given priority.

(2) We shall maintain a fair and healthy relationship with business partners and others, and shall not receive, request for or promise illegal or unjust benefits (money, goods, entertainment, favors, etc.) in relation to a position or power at work.

23. Shareholders and Investors

We shall disclose corporate information that is likely to influence share prices to shareholders and investors in a timely, appropriate and fair manner.

24. Elimination of Anti-Social Forces

We shall never have any relationship with anti-social forces including organized crime groups (*boryokudan*) and extortionists that threaten social order or safety. We shall reject all unjust demands by anti-social forces and firmly stand up against them.

25. Respect for Human Rights, Prohibition of Discrimination and Harassing Behavior, and Prohibition of Harassment

(1) We shall respect the human rights of all people, and understand and respect diverse values, personalities and individuality.

(2) We shall not discriminate or engage in harassment to anyone based on race, nationality, ethnic or social origin, ancestry, ethnicity, age, religion, faith or belief, sex and gender, sexual orientation, gender identity, marital status, academic background, disability, disease, employment status, or any other status.

(3) We shall not tolerate any form of harassment including sexual harassment and power harassment in the workplace so as to create a pleasant and comfortable working environment.

(4) We shall express our policies on respect for human rights to our business partners, including our suppliers and other relevant stakeholders, and request their understanding of such policies.

26. Compliance with Labor Laws and Regulations and Creation of a Working Environment

with Due Consideration to Safety and Health

(1) We shall comply with the Labor Standards Act, Industrial Safety and Health Act, Part-Time Workers Act and other labor laws and regulations. In addition, we shall make continued efforts for the prevention of industrial accidents and maintenance of employees' health by creating a working environment that gives consideration to safety and health and comfortable working conditions.

(2) We shall understand the spirit of the Health Promotion Act, and promote measures against passive smoking in the workplace.

(3) We shall be aware of the need for compliance in all aspects of business activities, including in the workplace, and shall not be engaged in such behaviors or gambling acts that may disgrace or discredit people inside and outside the Company. Furthermore, we shall ensure to drive safely and never drink and drive when we drive vehicles during work, commuting and on any other occasion.

(4) We shall ensure full compliance with laws and regulations related to employment so that the Company will not be engaged in illegal staffing dispatch or disguised contract labor.

27. Prohibition of Illegal and Personal Use of Company Assets

(1) We shall use funds, goods or other assets of the Company only for its business operations, and will not use them for illegal purposes or for individual or third party's interests.

(2) We shall effectively utilize the Company's information system and devices, and will not utilize them for individual or third party's interests.

28. Accuracy of Accounting Records, Ensuring the Credibility of Financial Reports, and Compliance with Tax Laws

(1) We shall accurately record business activities in preparing, creating and keeping accounting records and documents to be submitted to public offices.

(2) We shall develop, operate and evaluate an appropriate system for the internal control over financial reports to ensure the credibility of the financial reports.

(3) We shall always recognize that the payment of taxes is an obligation of citizens and shall observe tax laws.

29. Proper Handling of Intellectual Property Rights and Compliance with the Rules for Handling Inventions

(1) We shall respect the intellectual property rights of a third party equally as those of the Company, and shall not infringe the same.

(2) We shall observe rules concerning employee inventions (the Rules for Handling Inventions) and promote research and development activities.

30. Proper Handling of Confidential Information

(1) We shall recognize the importance of the confidential information of the Company acquired through business activities and shall properly manage such information.

(2) We shall not wrongfully obtain, use or disclose the confidential information of other companies and of any other third party.

We shall not disclose within the Company, or use for the Company, the confidential information of a third party that we had acquired prior to joining the Company and the confidential information of a third party that we had learned through temporary transfers and other similar arrangements.

(3) We shall properly manage confidential information in electronic format equally as confidential information in printed format.

(4) We shall not wrongfully use the confidential information of the Company and of other companies for our personal interests or any third party's interests.

31. Protection of Personal Information and Individual Numbers

(1) We shall recognize the importance of protecting personal information and individual numbers, and shall comply with applicable laws and regulations as well as internal rules. We shall also appropriately establish and manage a system to promote the protection of personal information and individual numbers and prevent the leakage thereof.

(2) We shall take necessary and appropriate measures to protect personal information and individual numbers, such as through the proper acquisition of personal information and individual numbers, notification and publication of the purpose of use, prohibition of use for unintended purposes, safe management, education of employees and others, restriction on the provision of such information to a third party, and the development and operation of procedures to respond to requests for actions, such as the disclosure of owned personal data.

32. Compliance with the Insider Trading Regulations, etc.

(1) We shall comply with insider trading regulations stipulated by the Financial Instruments and Exchange Act. If and when we learn of unpublished material facts regarding business and other activities of the Company, its parent company, subsidiaries, business partners and others (hereinafter simply referred to as the "Internal Information") in relation to our duties, we shall not trade in the shares of the relevant company, either personally or as a company, unless such fact is published through certain procedures. In addition, officers shall observe the restrictions on trading of the Company's own shares by officers, as provided under the Financial Instruments and Exchange Act.

(2) We shall strictly manage the Internal Information we learn of in relation to our duties, and shall not communicate relevant information or recommend relevant transactions to a third party unless necessary in relation to our duties.

33. Compliance Hotline

(1) We shall establish a compliance hotline and make efforts for the active use of the same in order to enhance the capacity of the organization for self-purification and promote compliance.

(2) When we receive any report or have any consultation through the compliance hotline, we shall appropriately handle such report and consultation.

(3) We shall not adversely treat persons who have used the compliance hotline on the basis of such use.

(4) We shall continuously review the compliance hotline including its system and operation in order to improve its effectiveness.