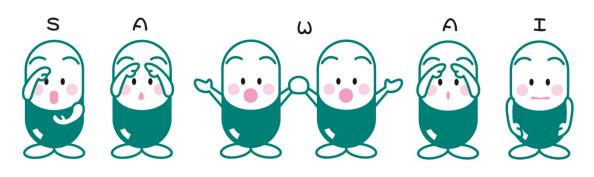


Procurement Guidelines



Patients First Sawai Pharmaceutical Co., Ltd.

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Procurement Guidelines

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These guidelines were prepared with reference to JEITA Supply Chain CSR Promotion Guidebook (2006) (JEITA: Japan Electronics and Information Technology Industries Association)

Basic Procurement Principles

In order to realize our corporate philosophy, "Patients First" we will carry out procurement activities by fairly selecting suppliers, based on quality, stable supply and economic rationality, whether in Japan or overseas.

In order to practice transactions evoking sympathetic responses from people, we will build up our relationship of trust with suppliers and aim at continuing to grow together.

Basic Procurement Policies

- 1. Transactions evoking sympathetic responses
- 2. Strict information management
- 3. Modest transaction relationships

Guideline Texts

1 Impartial and Fair Transactions

1.1 Prohibition against Unfair Competitive Inhibition Acts, etc.

Suppliers are requested to refrain from practices that restrict fair, transparent, and free competition.

"Restrictive trade practices" refers to prior agreements with companies in the same trade about the prices for products or services, quantities, sales areas, etc., (cartels). It also refers to prior arrangements with other bidders about the winning bidder and the successful tender price (collusive bidding).

1.2 Prohibition against Abuse of Superior Bargaining Position

Suppliers are requested to refrain from practices that create disadvantage for their own suppliers (sub-suppliers, from Sawai's perspective) by abusing their superior bargaining position.

"Abuse of a superior bargaining position" refers to such practices as taking advantage of one's superior position as a purchaser or consigner and unilaterally determining trading conditions, altering them, or imposing unreasonable requests or obligations. Suppliers are requested to refrain from abusing their superior bargaining position. Suppliers should conduct procurement transactions that are honest, fair, and impartial, and are based on formal agreements with their suppliers (sub-suppliers, from Sawai's perspective). When conducting business in countries that have legislation regarding abuse of superior bargaining position, suppliers are requested to comply with all such laws (for example, Japan's Act Against Delay in Payment of Subcontract Proceeds, etc., to Subcontractors).

1.3 Prohibition against Corruption and Bribery

Suppliers are requested to maintain healthy and normative relationships with governmental and administrative bodies and to refrain from bribery or illegal political donations.

"Bribery" refers to the act of offering benefits to public officials or equivalent persons (hereafter referred to as "public officials") in order to gain a business advantage. Examples of such benefits include money, hospitality, gifts. Examples of business advantages expected in return include a business license, an acquisition or continuation of trading, or access to non-disclosure information. Hospitality or gift-giving to public officials can constitute bribery even if no business advantage is sought in return.

1.4 Prohibition against Giving or Receiving of Improper Advantage

Suppliers are requested to refrain from giving to or receiving from their stakeholders any improper advantage.

"Stakeholders" are defined as parties that can be affected directly or indirectly by the commercial activities of a business. "Giving or receiving of improper advantage" refers to the following types of practices:

- Giving to or receiving from clients benefits that could be construed as bribes. For example, a gift, award, or prize money, etc., that exceeds the bounds determined by law or fair competition rules; or money, goods, or hospitality that exceeds the bounds of social courtesy.
- Giving improper advantage to an antisocial force that adversely affects public order and healthy activities (examples of such include gangs, criminal syndicates, and terrorist organizations, etc.)
- Insider trading by which stock of a company is traded based on non-disclosure information about the operations of a client, etc.

1.5 Respect for Intellectual Property

Suppliers are requested to refrain from infringing upon intellectual property rights.

"Intellectual property rights" (IPR) refers to patent rights, utility model rights, design rights, trademark rights, copyrights. It also refers to rights that are stipulated by laws and regulations on other intellectual property or rights related to trade secrets pertaining to interests that are protected by law. Before developing, producing, selling or providing any product or service, suppliers are requested to fully investigate the intellectual property of third parties concerned. Utilizing a third party's intellectual property without permission constitutes an infringement of IPR, except in cases where there is a justifiable reason. Illegally reproducing computer software or other copyrighted works also constitutes an infringement of IPR.

Likewise, illegally obtaining and utilizing the trade secrets of a third party also constitutes an infringement of IPR.

1.6 Prevention and Early Detection of Improper Practices

Suppliers are requested to conduct activities designed to prevent improper practices and to establish an early detection system.

"Activities to prevent improper practices" refers to efforts to train and raise awareness among staff and create a healthy workplace climate. "An early detection system" refers to a system of measures designed to detect and rectify improper practices at an early stage. Examples of such measures include the following:

- Establishing an in-house and external hotline for reporting improper practices so that top management can be alerted at early stage.
- Safeguarding the anonymity of whistle-blowers and protecting them as necessary.
- Responding swiftly to improper practices, and appropriately conveying the outcomes to the whistle-blower.

1.7 Proper Management of Export Shipping

Suppliers are requested to establish clear controls on the shipment of goods and technologies regulated by laws.

"Goods and technologies regulated by laws" refers to parts, finished products, technologies, facilities, and software etc., that are subject to export restrictions in accordance with international agreements such as the Wassenaar Arrangement (The Wassenaar Arrangement on Export Controls for Conventional Arms and Dual-Use Goods and Technologies). In some cases, authorization from supervisory authorities is required as part of the export shipping process.

2 Human Rights and Labor

2.1 Prohibition against Inhumane Treatment

Suppliers are requested to respect the human rights of employees and to prohibit abuse, harassment, and any other cruel and inhumane treatment.

"Cruel and inhumane treatment" refers to abuse, physical punishment, sexual harassment, and abuse of authority (for example, verbal abuse or high-handed behavior, often referred to in Japan as "power harassment.").

2.2 Prohibition against Discrimination

Suppliers are requested to eliminate discrimination in hiring and employment practices of employees, and to strive for equal opportunity and fair treatment.

"Discrimination" refers to the practice of treating a person differently or not giving them the same opportunity as others with respect to recruitment, promotion, rewards and participation in training based on factors other than their ability, suitability for the job, and performance, all of which would be considered "reasonable factors." Discrimination is based on "unreasonable factors" such as race, ethnicity, nationality, birthplace, color, age, gender, sexual orientation, disability, religion, political views, union membership, and marital status. If equality of opportunity or fair treatment are impaired by the result of health examinations, etc., it can also be construed as discrimination.

2.3 Prohibition against Forced Labor

Suppliers are requested to employ all employees of their own free will with no employee being subject to forced labor.

"Forced labor" refers to all types of employment performed not based on labor contracts but on a non-voluntary basis.

Examples of forced labor include the following:

- Forcing someone to work against their will.
- Bonded labor in which the person is restricted from leaving the employment because of a debt owed to the employer.
- Slave labor in which the person performing the work has been trafficked.
- Being restricted from leaving the employment.
- Imposing a duty on the employee to deposit their identification cards, passport, or work permit.

2.4 Prohibition against Child Labor

Suppliers are requested to refrain from employing as employees children who are under the minimum age of employment, and assigning any work that would impair a child's development. "Child labor" generally refers to the employment of persons who are under the minimum age of employment as specified by the International Labor Organization (ILO), Conventions and Recommendations on Child Labor, or the failure to duly protect young employees.

Examples of practices that run afoul of the prohibition against child labor in Japan include the employment of persons who upon reaching the age of 15 years old have not passed the first March 31 date, and violations of laws designed to protect young employees. The law protects young employees from work that would pose a threat to their health, safety, or moral integrity by, for example, setting restrictions on nighttime work and dangerous work. Overseas business operations will be deemed to be using child labor if they involve the employment of persons who are under the minimum age of employment, or if they violate duty of protection as determined by local laws.

If the country concerned has no such law, then business operations in that country will be deemed to be using child labor if they violate the ILO provision on the minimum age of employment (15 years is the minimum age for child work: ILO ConventionNo.138.).

2.5 Respecting Employees' Right to Organize

Suppliers are requested to respect employees' right to organize in order to bring about negotiations between labor and management over working conditions or wage standards, etc., of employees.

"Respect employees' right to organize" means honoring employees' freedom to associate, participate in a labor union in accordance with laws, stage protests, and participate in workers' council, and to do these things without fear of retaliation, intimidation, or harassment.

2.6 Working Hours

Suppliers are requested to appropriately manage employees' working hours, days off, and leave to ensure that employees' working hours are within the bounds stipulated by law.

"Appropriately manage employees' working hours" refers to the following:

- Ensuring that scheduled working days are within the bounds stipulated by law.
- Ensuring that working hours per week are within the bounds stipulated by law. This
 also applies to overtime except in cases of emergency.
- Providing employees with days off and annual paid leave in accordance with work rules and laws.

2.7 Appropriate Wages

Suppliers are requested to pay employees no less than the legal minimum wages, and to refrain from practicing improper wage reduction as a means of disciplinary action.

"Minimum wages" refers to the minimum level of wages as determined by the wage-related laws of the country concerned. As used here, the term includes the payment of other allowances, including overtime compensation and legal payments. "Improper wage reduction" refers to wage reductions that violate labor-related laws, etc.

3 Health and Safety

3.1 Safety in the Workplace

Suppliers are requested to assess safety risks in the workplace and to use appropriate designs, techniques, and control measures to secure safety.

"Safety risks in the workplace" refers to the potential risks of accidents or injuries to health occurring in the course of work. Examples of risks include electricity or other types of energy, flammable material, vehicles, slippery/easy-to-stumble floors, and falling objects.

Examples of "appropriate designs, techniques, and control measures" include the following:

- Using sensors to monitor hazardous areas.
- Using the safety hasp to isolate hazardous machinery from power sources (lock-out).
- Affixing a tag to the locked machinery indicating that it should not be turned on (tag-out).
- Providing protective equipment such as glasses, hard hats, and gloves.

3.2 Safety Measures for Machinery and Equipment

Suppliers are requested to establish appropriate safety measures with respect to machinery and equipment used by employees.

As used here, the phrase "appropriate safety measures" refers to the practice of managing machinery and equipment so as to prevent accidents and health problems occurring in the course of work. Examples of such include the following:

- Adopting safety mechanisms such as fail-safe, foolproof, and inter-lock.
- Installing safety devices and protective barriers.

- Carrying out periodic inspection and maintenance.

3.3 Hygiene in the Workplace

Suppliers are requested to identify situations in which employees are exposed to harmful organisms, substances, noises, or odors, and to establish appropriate measures.

Examples of "harmful" substances include chemical substances such as smoke, vapor, mist, dust, and substances that are toxic, radioactive, or cause chronic disease (such as lead and asbestos). Noises and odors can also be construed as "harmful" if they are particularly problematic.

Examples of "appropriate measures" include the following:

- Identifying and assessing situations where employees are exposed to harmful substances or conditions.
- Establishing and enforcing safety management criteria.
- Providing appropriate training.
- Providing protective devices.

3.4 Occupational Accidents and Disease Resulting from Employment

Suppliers are requested to understand the situation concerning occupational accidents and disease resulting from employment, and to establish appropriate measures.

Examples of "appropriate measures" include the following:

- Encouraging employees to declare accidents and disease.
- Keeping records of accidents and diseases.
- Providing emergency measures as necessary.
- Conducting surveys on accidents and disease.
- Taking proactive steps to eliminate the causes of accidents and disease.
- Facilitating an injured employee's rehabilitation and return to work.
- Subscribing to workers' compensation insurance.
- Undertaking administrative procedures as stipulated by law.

3.5 Giving Due Consideration to Physically Demanding Work

Suppliers are requested to specify physically demanding work and to appropriately manage workloads to prevent accidents or disease.

Examples of "physically demanding work" include the following:

- Heavy labor such as lifting and carrying heavy objects.

- Repetitive or lengthy operations such as product assembly or data entry.

"Appropriately manage" refers to such measures as allowing workers to take short breaks, providing them with auxiliary tools, and ensuring that the workload is shared appropriately.

3.6 Health and Safety in Facilities

Suppliers are requested to appropriately safeguard health and safety in facilities provided to employees (company housing, cafeterias, and restrooms, etc.).

"Facilities provided to employees" refers to workplace facilities (including restrooms, water coolers, locker rooms, and cafeterias) and facilities external to the workplace (such as company housing).

Health and safety in such facilities is safeguarded by, for example, ensuring that they are clean and sanitary, and that they have safe drinking water, fire safety systems, ventilation and temperature control, emergency exits, safe ways to store personal belongings, and access to emergency medical treatment.

3.7 Employee Health Management

Suppliers are requested to carry out appropriate health management with respect to all employees.

"Appropriate health management" refers to efforts made to prevent or detect early on diseases among employees by providing at the very least medical checkups as per standards set by law. It is also necessary to prevent health problems associated with overwork and give due consideration to mental health care.

3.8 Education and Training for Safety and Hygiene

Suppliers are requested to provide education and training in a language understandable to employees concerning safety information of pharmaceuticals and their intermediary bodies and any other hazardous substance and occupational safety.

"Safety information" refers to SDS (Safety Data Sheet) or similar information and to preparing the environment in which employees can easily refer to such information. Education and training should be provided thoroughly and continuously for appropriate use and handling method, storage method and disposal method, etc., depending on the nature of each employee's job (related laws, manufacturing equipment, handling substances and employee composition, etc.).

3.9 Emergency Measures

In order to protect the welfare of employees, suppliers are requested to prepare emergency measures as a precaution against possible disasters or accidents, and to ensure that they are fully understood throughout the workplace.

Examples of "emergency measures" include the following:

- Issuing an alert when disaster strikes.
- An employee notification system.
- Clarification of evacuation procedure.
- Setting up of evacuation facilities.
- Storing emergency medical products.
- Installation of a fire alarm system and fire extinguishers.
- Securing an external communication method.
- A recovery plan.

Examples of ensuring that these measures are "fully understood throughout the workplace" include the following activities:

- Providing emergency training to employees (including evacuation drills).
- Displaying emergency response procedures in places where they can be easily accessed by employees.

4 Concern for the Environment

4.1 Report on Implementation and Outcomes of Environmental Activities

Suppliers are requested to a disclose report on implementation and outcomes of environmental activities as necessary.

As used here, the term "environmental activities" means developing an environmental policy, implementing the necessary measures to realize such a policy, and maintaining these measures, reviewing and revising them as necessary. In this way, environmental activities should follow the PDCA cycle (Plan, Do, Check and Action) and be continuously improved.

Examples of "outcomes of environmental activities" include the following:

- Progress made toward environmental conservation.
- Emissions of air, water, and soil pollutants.
- Resource consumption volume.
- Volume of waste generated.
- Impact to environment from daily operations in factories and business sites.

Outcomes should be periodically assessed by establishing a system for facilitating

environmental activities, appointing the appropriate personnel, and making continuous records. Such records should show outcomes according to environmental management indicators, level of attainment, and other environmental indices. Outcomes should be disclosed by releasing environmental reports, integrated reports, CSR reports, etc., to the public, and reporting to stakeholders as necessary.

4.2 Environmental/Government Permits

Suppliers are requested to obtain permits from governmental bodies in cases where they are required by local laws, and to submit the necessary reports to such bodies.

The following are examples of Japanese laws that require companies to appoint officers with certain qualifications:

- Waste Management and Public Cleansing Law: Specially Controlled Industrial Waste Manager.
- Act on the Rational Use of Energy: Qualified Energy Manager (in factories that use a certain level of energy).
- Air Pollution Control Act: Pollution Prevention Manager (in factories that emit chemical substances, dust, and exhaust fumes).

Companies in Japan are also obligated to appoint officers in charge of toxic/deleterious substances, specified chemical substances, and hazardous materials.

Depending on the type of business and location, companies may be required to undergo an environmental impact assessment and obtain a permit for facilities handling hazardous material.

4.3 Control of Chemical Substances

Suppliers are requested to control hazardous chemical substances that are used in manufacturing processes and have been specified in laws and regulations of the country concerned.

"Control hazardous chemical substances that are used in manufacturing processes" refers to the control of chemical substances used in products. It also means ascertaining the volumes of chemical substances discharged to the environment, reporting such data to governmental bodies, and making efforts to reduce them to acceptable levels.

4.4 Minimization of Impact on the Environment (drainage, emissions, sludge)

Suppliers are requested to comply with laws and regulations on drainage, emissions and sludge in the country concerned, and to make further improvements to voluntary standards as necessary. "Voluntary standards" refers to voluntarily-set goals to reduce impact on the environment at least to the levels stipulated by laws and regulations. While the basic aim is to prevent environmental damage from occurring, there is always room for further improving standards by, for example, improving the monitoring, control, and processing of drainage, emission, and sludge with a view to reducing the output of such.

4.5 Waste Reduction (3R's)

Suppliers are requested to set voluntary targets for waste reduction and to pursue continuous waste reduction.

"Waste" refers to materials that are no longer needed at the factory or business site, and as such are discharged into the environment. Examples of "continuous waste reduction" activities include formulating voluntary targets for reducing the volume of waste output, drawing up plans to achieve these targets, and vigorously executing such plans. It is important to always be mindful of the "3 R's" –Reduce (reducing the generation of waste), Reuse (reuse), and Recycle (recycling).

4.6 Effective Utilization of Resources and Energy

Suppliers are requested to set voluntary targets for resource-conservation and energy-conservation, and to strive to effectively utilize resources and energy on an ongoing basis.

"Resource-conservation" refers to steps taken toward the effective utilization of resources. Examples of such steps include the following.

- Reducing the amount of materials used in the manufacture of products.
- Utilizing recycled resources.

"Energy-conservation" refers to steps taken toward the rational utilization of thermal and electrical energy. Cutting down on wasteful energy consumption will ensure the effective utilization of fuel such as oil, natural gas, coal, and coke.

5 Product Quality and Safety

5.1 Securing Product Safety

For pharmaceuticals and raw materials and manufacturing devices thereof, etc., suppliers are requested to ensure that the products satisfy safety standards established under laws and regulations in the countries concerned.

When undertaking product design, suppliers are requested to ensure that the design is sufficiently safe, and to conduct marketing with full awareness of their responsibility as a manufacturer. Suppliers should also comply with laws, standards, and norms concerning product safety. As the laws concerning product safety, there are the Pharmaceuticals and Medical Devices, etc., Act, GXP, FSSC 22000, REACH Regulations, UL, Product Liability Act, Electrical Appliance and Material Safety Act, Consumer Products Safety Act, Household Goods Quality Labeling Act, etc. The safety standards are provided for in detailed regulations of the laws and JIS, etc. "Securing product safety" refers to such practices as managing traceability (understanding the raw materials and parts used to make the product, and the manufacturing processes involved) and resolving product safety issues promptly.

5.2 Quality Management System

Suppliers are requested to establish and run a quality management system.

"Quality Management System" (QMS) refers to a comprehensive management system for promoting quality assurance activities, and it involves organizational structures, planning activities, division of responsibilities, practices, procedures, processes, and managerial resources.

The term "quality assurance activities" means developing a quality assurance policy, implementing the necessary measures to realize such a policy, and maintaining these measures, reviewing and revising them as necessary. In this way, quality assurance activities should follow the PDCA cycle (Plan, Do, Check and Action) and be continuously improved. Key examples of the certification of QMS include the ISO 9000 family, ISO 15378, ISO 22000, and ISO 13485.

The requirements for manufacture and sale of pharmaceuticals are to establish the pharmaceuticals product quality system, determine the basic policy for "quality" to operate it effectively and to carry out continuous improvement of the quality and stable supply of pharmaceuticals.

5.3 Control of Chemical Substances Contained in Products

With respect to all of their products, suppliers are requested to control chemical substances specified in the laws of countries in which the products concerned are manufactured, imported to, or used.

"Controlling chemical substances contained in products" involves confirming whether a product contains any chemical substances that are prohibited or controlled in local laws, and in the case that it does, ascertaining the volume(s) of the substance(s) it contains. It also involves complying with any obligations to report or display information about

such substances, and applying for registration or submitting the product for testing if necessary.

5.4 Provision of Accurate Information on Products and Services

Suppliers are requested to provide consumers and clients with accurate information about their products and services.

Providing "accurate information" involves the following:

- Ensuring the accuracy of information about products or services, including specifications, quality, and handling.
- Ensuring the accuracy of information about substances contained within products and their components.
- Ensuring that promotional material such as catalogs and advertisements do not contain any phrases that are inaccurate or would cause misunderstanding among consumers and clients, or any content that slanders or infringes the rights of companies or individuals.

6 Information Security

6.1 Protection from Threats to Computer Networks

Suppliers are requested to establish protective measures against threats to computer networks to prevent any harm arising in their company or other companies.

Examples of "threats to computer networks" include viruses, worms, and spyware.

If a computer connected to the Internet gets infected by a virus, etc., there is a risk that client information and other sensitive information stored on that computer will be leaked. The infected computer may also attack another company's computer system, which would bring about serious damage such as an operational standstill and loss of confidence.

6.2 Prevention of Leakage of Personal Information

Suppliers are requested to appropriately manage and protect the personal information of clients, third parties, and employees.

"Personal information" refers to information about a living individual that includes the person's name, date of birth, or any other detail by which the person can be identified (including such information that will allow easy reference to other information and thereby enable the identification of the specific individual.)

"Appropriate management of personal information" refers to the establishment and

operation of a comprehensive framework for the management of personal information. This includes the creation of regulations and guidelines to be observed by employees, the drawing up of plans, the implementation of programs, internal audits, and reviews based on such a framework.

"Appropriate protection" means ensuring that personal information is not improperly or unjustly obtained, utilized, disclosed, or leaked.

6.3 Prevention of Leakage of Confidential Information about Clients and Third Parties

Suppliers are requested to appropriately manage and protect confidential information regarding clients and third parties.

"Confidential information" generally refers to information that is displayed in a written document (including electromagnetic or optically recorded data) after it is agreed that such information is confidential, or information that is disclosed orally after notice has been made as to the confidential nature of such information.

"Appropriate management of confidential information" refers to the construction and operation of a comprehensive framework for the management of confidential information. This includes the creation of regulations and guidelines to be observed by employees, the drawing up of plans, the implementation of programs, internal audits, and reviews based on such a framework.

"Appropriate protection" means ensuring that confidential information is not improperly or unjustly obtained, utilized, disclosed, or leaked.

7 BCP (Business Continuity Plan)

7.1 Disaster-Preparedness Measures

Suppliers are requested to establish BCP (Business Continuity Plan).

A "BCP" (Business Continuity Plan) is a disaster-preparedness measure for ensuring the continuation of important business in disaster situations. Examples of "disaster situations" include natural disasters such as major earthquakes and pandemics. Having a BCP will enable smooth recovery from a disaster situation. Another advantage is that preparing such a plan will prompt analysis of risks of business operations, which may lead to managerial improvements.

8 Disclosure of Information

8.1 Disclosure of Information to Stakeholders

Suppliers are requested to proactively disclose information to stakeholders irrespective of whether or not such disclosure is mandated by law.

Examples of information that should be disclosed to stakeholders include the following:

- Business activities.
- Financial information.
- Business performance.
- Risk information (such as information on damage from large-scale disaster, occurrence of events that adversely impact the environment or society, and serious infringements of laws or regulations.)

An example of proactive information provision is promptly disclosing information about serious risks and providing such information to clients.

9 Social Contribution

9.1 Contribution to the Community

Suppliers are requested to voluntarily carry out activities designed to contribute to the development of the local and global community.

"Activities designed to contribute to the development of the local and global community" refers to schemes that use corporate resources to support the community. The following are typical examples of social contributions:

- Social contributions made through applying the company's original business model and its technology.
- Non-monetary social contributions made through using the company's facilities or human resources.
- Social contributions made through monetary donations.

Social contributions involve the following types of activities:

- Cooperating with the local community in times of disaster.
- Voluntary activities performed by employees.
- Monetary or non-monetary contributions to NPO's or NGO's.
- Providing useful information.

Suppliers should determine the extent of the contributions they can make and then carry them out proactively.