

THE PSCI PRINCIPLES FOR RESPONSIBLE SUPPLY CHAIN MANAGEMENT

This document outlines the PSCI Principles for Responsible Supply Chain Management (the “Principles”) for human rights*, ethics, labor, health and safety, environment and related management systems. The Principles may be voluntarily supported by any business in the pharmaceutical industry.

Companies supporting the Principles:

- will integrate and apply these Principles in a manner consistent with their own supplier programs.
- understand that society and business are best served by responsible business behaviors and practices. Fundamental to this understanding is that a business must, at a minimum, operate in full compliance with all applicable laws, rules and regulations.
- are aware of differences in culture and the challenges associated with interpreting and applying these Principles globally. While companies supporting the Principles understand that what is expected is universal, it is understood that the methods for meeting these expectations may differ dependent on size and location.
- understand the Principles are best implemented through a continual improvement approach that advances supplier performance over time.

The [PSCI Implementation Guide](#) provides examples of business practices and performance related to the Principles.

*The term “human rights” in these Principles is defined in accordance with the UN Guiding Principles on Business and Human Rights, which we accept as the internationally agreed standard for the corporate responsibility to respect human rights. The PSCI supports the UNGPs and will offer and promote implementation guidance to members and the pharmaceutical sector to encourage their widest adoption.

Ethics

Suppliers shall conduct their business ethically and act with integrity. The Ethics elements include:

1. ANTI-BRIBERY AND CORRUPTION

All forms of bribery, corruption*, extortion and embezzlement are prohibited. Suppliers shall not pay or accept bribes or participate in other illegal inducements in business or government relationships, or through the use of intermediaries. Suppliers shall ensure they have adequate systems in place to prevent bribery and comply with applicable laws.

2. FAIR COMPETITION

Suppliers shall conduct their business consistent with fair and vigorous competition and in compliance with all applicable anti-trust laws. Suppliers shall employ fair business practices including accurate and truthful advertising.

3. ANIMAL WELFARE

Animals shall be treated humanely with pain and stress minimized. Animal testing should be performed after consideration to replace animals, to reduce the numbers of animals used, or to refine procedures to minimize distress. Alternatives should be used wherever these are scientifically valid and acceptable to regulators.

4. DATA PRIVACY AND SECURITY

Suppliers shall safeguard and make only proper use of confidential information to ensure that company, worker, patient, subject* and donor* privacy rights are protected. Suppliers shall comply with applicable privacy and data protection laws and ensure the protection, security and lawful use of personal data.

5. PATIENT SAFETY AND ACCESS TO INFORMATION

Suppliers shall ensure that adequate management systems are in place to minimize the risk of adversely impacting on the rights of patients, subjects and donors, including their rights to health and to access information directly.

6. CONFLICTS OF INTEREST

Suppliers shall take reasonable care to avoid and manage conflicts of interest. Suppliers are expected to notify all affected parties if an actual or potential conflict of interest arises.

*We use the term “corruption” in these Principles to refer to the abuse of entrusted power for private gain, the term “subject” to refer to any person who participates as a subject in scientific and

medical experimentation or product testing, and the term “donor” to refer to any person who donates tissues, cells, organs and any other body parts for research purposes.

Human Rights and Labor

Suppliers shall be committed to uphold the human and employment rights of workers and to treat them with dignity and respect. The Labor elements include:

1. FREELY CHOSEN EMPLOYMENT

Suppliers shall not use forced, bonded or indentured labor or involuntary prison labor. No worker shall pay for a job or be denied freedom of movement.

2. CHILD LABOR AND YOUNG WORKERS

Suppliers shall not use child labor. The employment of young workers below the age of 18 shall only occur in non-hazardous work and when young workers are above a country's legal age for employment or the age established for completing compulsory education.

3. NON-DISCRIMINATION

Suppliers shall provide a workplace free from discrimination. There shall be no discrimination for reasons such as race, color, age, pregnancy, gender, sexual orientation, ethnicity, disability, religion, political affiliation, union membership or marital status.

4. FAIR TREATMENT

Suppliers shall provide a workplace free of harassment, harsh and inhumane treatment, including any sexual harassment, sexual abuse, corporal punishment, mental or physical coercion or verbal abuse of workers and no threat of any such treatment.

5. WAGES, BENEFITS AND WORKING HOURS

Suppliers shall pay workers according to applicable wage laws, including minimum wages, overtime hours and mandated benefits.

Suppliers shall communicate with the worker the basis on which they are being compensated in a timely manner. Suppliers are also expected to communicate with the worker whether overtime is required and the wages to be paid for such overtime. Overtime shall be consistent with applicable national and international standards.

6. FREEDOM OF ASSOCIATION

Open communication and direct engagement with workers to resolve workplace and compensation issues is encouraged.

Suppliers shall respect the rights of workers, as set forth in local laws, to associate freely, join or not join labor unions, seek representation and join workers' councils. Workers shall be able to communicate openly with management regarding working conditions without threat of reprisal, intimidation or harassment.

Health and Safety

Suppliers shall provide a safe and healthy working environment, including - where applicable - for any company-provided living quarters. Health and Safety measures shall extend to contractors and subcontractors on supplier sites. The Health and Safety elements include:

1. WORKER PROTECTION

Suppliers shall protect workers from over exposure to chemical, biological, physical hazards and physically demanding tasks in the workplace and in any company provided living quarters. Suppliers shall ensure appropriate housekeeping and provide workers with access to potable water.

2. PROCESS SAFETY

Suppliers shall have management processes in place to identify the risks from chemical and biological processes and to prevent or respond to catastrophic release of chemical or biological agents.

3. EMERGENCY PREPAREDNESS AND RESPONSE

Suppliers shall identify and assess emergency situations in the workplace and any company provided living quarters, and to minimize their impact by implementing emergency plans and response procedures.

4. HAZARD INFORMATION

Safety information relating to hazardous materials - including pharmaceutical compounds and pharmaceutical intermediate materials - shall be available to educate, train, and protect workers from hazards.

Environment

Suppliers shall operate in an environmentally responsible and efficient manner to minimize adverse impacts on the environment. Suppliers are encouraged to conserve natural resources, to avoid the use of hazardous materials where possible and to engage in activities that reuse and recycle. The Environmental elements include:

1. ENVIRONMENTAL AUTHORIZATIONS AND REPORTING

Suppliers shall comply with all applicable environmental regulations. All required environmental permits, licenses, information registrations and restrictions shall be obtained, and their operational and reporting requirements followed.

2. WASTE AND EMISSIONS

Suppliers shall have systems in place to ensure the safe handling, movement, storage, disposal, recycling, reuse, or management of waste, air emissions and wastewater discharges. Any waste, wastewater or emissions with the potential to adversely impact human or environmental health shall be appropriately managed, controlled and treated prior to release into the environment. This includes managing releases of active pharmaceuticals into the environment (PiE).

3. SPILLS AND RELEASES

Suppliers shall have systems in place to prevent and mitigate accidental spills and releases to the environment and adverse impacts on the local community.

4. RESOURCE USE

Suppliers shall take measures to improve efficiency and reduce the consumption of resources.

5. SUSTAINABLE SOURCING AND TRACEABILITY

Suppliers shall carry out due diligence on the source of critical raw materials to promote legal and sustainable sourcing.

Management Systems

Suppliers shall use management systems to maintain business continuity, facilitate continual improvement and compliance with the expectations of these principles. The Management System elements include:

1. COMMITMENT AND ACCOUNTABILITY

Suppliers shall demonstrate commitment to the concepts described in this document by allocating appropriate resources and identifying senior responsible personnel.

2. LEGAL AND CUSTOMER REQUIREMENTS

Suppliers shall identify and comply with applicable laws, regulations, standards and relevant customer requirements.

3. RISK MANAGEMENT

Suppliers shall have mechanisms to determine and manage risks in all areas addressed by these Principles.

4. DOCUMENTATION

Suppliers shall maintain documentation necessary to demonstrate conformance with these Principles and compliance with applicable regulations.

5. TRAINING AND COMPETENCY

Suppliers shall have a training program that achieves an appropriate level of knowledge, skills and abilities in management and workers to address the expectations in these Principles.

6. CONTINUAL IMPROVEMENT

Suppliers are expected to continually improve by setting performance objectives, executing implementation plans and taking necessary corrective actions for deficiencies identified by internal or external assessments, inspections, and management reviews.

7. IDENTIFICATION OF CONCERNS

All workers shall be encouraged to report concerns, illegal activities or breaches of these Principles in the workplace without threat of or actual reprisal, intimidation or harassment. Suppliers shall investigate and take corrective action if needed.

8. COMMUNICATION

Suppliers shall have effective systems to communicate these Principles to workers, contractors and suppliers.