THE PSCI PRINCIPLES FOR RESPONSIBLE SUPPLY CHAIN MANAGEMENT

This is the third revision of the PSCI Principles, adopted by PSCI members in 2023. The Principles are foundational, setting members' expectations of suppliers, and form the base for all PSCI's tools and materials. The Principles are expected to apply to all locations engaged in supply to PSCI members, along with ancillary facilities such as worker accommodation when provided.

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, but in many cases, responsibility means going beyond these.
- understand the Principles are best implemented through a continual improvement approach that advances supplier performance over time.

PSCI's topic-specific maturity models and learning plans are available to guide suppliers towards better practices.

*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.

Glossary: Any word identified in the text with an asterisk (*) is defined in the Glossary at the end of the Principles.

Governance and Management Systems

Good governance and management systems are the foundation for compliance with all the PSCI Principles. Suppliers shall use appropriate systems to conduct due diligence* on risk and impact, monitor legislation, set priorities, assign responsibility, adopt risk-mitigation measures, and facilitate continual improvement and compliance. The Governance and Management Systems Principles are:

1. CULTURE, COMMITMENT, AND ACCOUNTABILITY

Suppliers shall demonstrate commitment to the concepts described in this document by allocating appropriate resources and identifying senior responsible personnel, thereby creating a culture* of responsible practices.

2. LEGAL AND CUSTOMER REQUIREMENTS

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

3. RISK MANAGEMENT

Suppliers shall have mechanisms to determine and manage risks in all areas addressed by these Principles. Suppliers shall have a management of change process in place to evaluate and control the risk of change.

4. TRACEABILITY AND CONTROL

Suppliers shall have systems in place to carry out due diligence* on their own supply chain, including traceability for the sources of raw materials to support legal and sustainable sourcing.

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. DOCUMENTATION

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

7. CONTINUAL IMPROVEMENT

Suppliers are expected to continually improve by setting performance objectives and executing implementation plans. Suppliers shall take necessary corrective actions for deficiencies identified by

internal or external assessments, inspections, and management reviews, including the recording and reporting of near-misses, incidents, and incident prevention opportunities.

8. EMERGENCY PREPAREDNESS AND RESPONSE

Suppliers shall have effective emergency plans and response procedures.

9. GRIEVANCE MECHANISMS

Suppliers shall establish grievance mechanisms accessible to internal and external stakeholders* who shall be encouraged to use them to report concerns, illegal activities or breaches of these Principles at work without threat of or actual reprisal, intimidation, or harassment.

10. RESPONSE AND REMEDIATION

Suppliers shall properly investigate incidents or concerns relating to these Principles, take necessary corrective actions, and provide remediation where required.

11. EFFECTIVE COMMUNICATION

Suppliers shall have effective systems to communicate these Principles to relevant stakeholders including their workers, contractors, suppliers, and local communities*.

Ethics

Suppliers shall conduct their business responsibly, ethically, and act with integrity. The Ethics Principles are:

1. 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.

2. ANTI-BRIBERY* AND CORRUPTION*

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

3. 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.

4. 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.

5. 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.

6. AVOIDANCE AND MANAGEMENT OF CONFLICTS OF INTEREST

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

7. PRODUCT PROTECTION AND QUALITY

Suppliers shall ensure that management and security systems protect products, components, and ingredients from the risks of adulteration, falsification, or theft for the purpose of illegal resale.

Human Rights

Suppliers shall be committed to respect the human rights* of internal and external stakeholders* ensuring to treat them with dignity and respect. These Principles describe the rights on which businesses may have the most common and direct adverse impacts. PSCI member companies commit to regularly assess all adverse human rights* impacts they may cause or contribute to, through their own business practices, including purchasing and other supply chain practices. The Human Rights Principles are:

1. FREELY CHOSEN EMPLOYMENT

Suppliers shall not use forced, bonded or indentured labor, involuntary prison labor, or take part in human trafficking or any form of modern slavery. 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 strive for equality, providing a work environment free from 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 work environment 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 and agreed employment contracts, 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. Overtime work shall be voluntary, as well as consistent with applicable national and international standards. Suppliers are expected to communicate with the worker whether overtime is required and the wages to be paid for such overtime.

6. FREEDOM OF ASSOCIATION AND RIGHT TO COLLECTIVE BARGAINING

Open communication and direct engagement with workers (i.e. social dialogue*) to resolve workplace and compensation issues are 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, as well as to bargain collectively. Where the right to freedom of association and collective bargaining is restricted under law, the employer facilitates, and does not hinder, the development of parallel means for independent and free association and bargaining. Workers shall be able to communicate openly with management regarding working conditions without fear of retaliation.

7. LOCAL COMMUNITIES*

Suppliers shall respect the rights of the local communities* around their sites including the right to a clean and healthy environment.

Health and Safety

Suppliers shall provide a safe and healthy working environment and support the wellbeing of workers. Health and Safety measures shall extend to contractors and subcontractors on supplier sites. The Health and Safety Principles are:

1. SAFETY OF THE WORK ENVIRONMENT

Adequate risk assessments and emergency plans shall be in place to ensure the safety of the work environment. Safety information relating to hazardous materials – including pharmaceutical compounds and pharmaceutical intermediate materials – shall be available and used to educate, train, and protect workers from hazards. Suppliers shall demonstrate good housekeeping practice and a culture* of safety.

2. WORKER PROTECTION, HEALTH, AND WELLBEING

Suppliers shall protect workers from over exposure to chemical, biological, and physical hazards*. Appropriate equipment, facilities, and services shall be provided to support worker safety, health, and wellbeing.

3. PROCESS SAFETY

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

Environment

Suppliers shall operate in an environmentally responsible and efficient manner to minimize adverse impacts on the environment, and to help their own suppliers do the same. Suppliers are encouraged to conserve natural resources, reduce greenhouse gas (GHG) emissions, preserve biodiversity and clean water, and minimize and control the use of hazardous materials. The Environment Principles are:

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. MANAGEMENT OF WASTE AND EMISSIONS

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. CLIMATE CHANGE

Suppliers shall monitor and reduce their GHG emissions* and support their suppliers to do the same.

4. RESOURCE EFFICIENCY

Suppliers shall strive for circularity, designing out waste, taking measures to improve efficiency and reduce the consumption of resources, including water, favoring renewable* and sustainable* sources. They shall also take measures to reuse and recycle.

5. BIODIVERSITY CONSERVATION

Suppliers shall understand their impacts on biodiversity*, reducing and mitigating their footprint wherever possible.

6. SPILLS AND RELEASES PREVENTION

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

GLOSSARY

Please note:

- *The definitions in the Glossary below are provided for guidance only and are not part of the PSCI Principles.*
- *The definitions were drafted by PSCI subject matter experts, based on robust international sources (see footnotes for detail).*

- Biodiversity[1]: The variability among living beings from all sources including, inter alia, aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species and of ecosystems.
- Bribery[2]: The offering, giving, soliciting, or receiving of any item of value as a means of influencing the actions of an individual holding a public or legal duty.
- Circularity[3]: A systems solution framework that tackles global challenges like climate change, biodiversity loss, waste, and pollution. It is based on three principles, driven by design: eliminate waste and pollution, circulate products and materials (at their highest value), and regenerate nature.
- Corruption[4]: The abuse of entrusted power for private gain and / or illicit benefits.
- Culture[5]: Combination of the attitudes, values, and beliefs of an organization that influence how it operates or how it reacts.
- Donor[6]: Any person who donates tissues, cells, organs, and any other body parts for research purposes.
- Due diligence[7]: Research and analysis of a company or organization done in preparation for a business transaction or as part of operational reviews.
- External stakeholder[8]: A person or an organization outside a particular company who has a vested interest in and / or is affected by its activities, including customers, suppliers, investors, or local communities.

[1] Convention on Biological Diversity
[2] Cornell Law School – Legal Information Institute
[3] Ellen McArthur Foundation
[4] Transparency International
[5] UK Government's Health and Safety Executive Science and Research Centre
[6] Version 2 of the PSCI Principles
[7] Merriam Webster Dictionary
[8] Cambridge Dictionary

- **Greenhouse Gas (GHG) emissions**[9]: Emissions from the six GHGs covered by the United Nations Framework Convention on Climate Change (Carbon dioxide (CO2); Methane (CH4); Nitrous oxide (N2 O); Hydrofluorocarbons (HFCs); Perfluorocarbons (PFCs); and Sulphur hexafluoride (SF6)) which contribute to global warming and climate change.
- **Human Rights**[10]: As laid out in the United Nations Guiding Principles on Business and Human Rights (UNGPs), human rights are defined, at a minimum, as the rights expressed in the International Bill of Human Rights and the International Labor Organization's Declaration on Fundamental Principles and Rights at Work.
- **Internal stakeholder**[11]**:** A person who works for and / or owns a company.
- **Local community**[12]**:** The people living and / or working in areas around a company's operations and activities.
- **Physical hazards**[13]**:** Factors within the environment that can harm the body without necessarily touching it.
- **Recognized standards**[14]**:** Generally accepted management systems and / or specifications emanating from international organizations.
- **Renewable resources**[15]: Renewable resources are an energy source that cannot be depleted and are able to supply a continuous source of clean energy.
- **Social dialogue**[16]**:** All types of negotiation, consultation, or simply exchange of information between, or among, representatives of governments, employers, and workers, on issues of common interest relating to economic and social policy.
- **Subject**[17]: Any person who participates as a subject in scientific and medical experimentation or product testing.
- **Sustainable resource use**[18]**:** Use of resources in a way and at a rate that does not lead to the long-term degradation of the environment, thereby maintaining its potential to meet the needs and aspirations of present and future generations.

[9] Kyoto Protocol to the United Nations Framework Convention on Climate Change
[10] United Nations Guiding Principles on Business and Human Rights
[11] Cambridge Dictionary
[12] Cambridge Dictionary
[13] United States Occupational Safety and Health Administration
[14] PSCI Management Systems experts' definition
[15] National Geographic
[16] International Labor Organization
[17] Version 2 of the PSCI Principles
[18] United Nations Environment Programme