THE PSCI PRINCIPLES FOR RESPONSIBLE SUPPLY CHAIN MANAGEMENT

This is the fourth revision of the PSCI Principles, adopted by PSCI members in 2026.

Mission: The PSCI Principles reflect a shared commitment by the pharmaceutical industry to respect human rights, protect the environment, and operate responsibly across global supply chains.

Expectations: PSCI Members expect suppliers and business partners to align with these Principles and integrate them into their operations and management systems. PSCI Members also uphold the Principles in their own operations.

Cascading: Suppliers are expected to promote these standards within their own supply chains.

Continuous Improvement: Responsible business is a process of continuous improvement. Suppliers are expected to strengthen their practices over time, going beyond minimum legal requirements where necessary. PSCI's topic-specific maturity models and learning plans are available to guide suppliers towards better practices.

Five Pillars: These Principles define responsible supply chain management across five interconnected areas:

1. Ethics
2. Human Rights
3. Health and Safety
4. Environment
5. Management Systems

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. LEADERSHIP, GOVERNANCE & 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. COMPLIANCE OBLIGATIONS & REQUIREMENTS

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

3. RISK & OPPORTUNITY MANAGEMENT

Suppliers shall have mechanisms to determine and manage risks and opportunities 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. DUE DILIGENCE*

Suppliers shall implement a risk-based due diligence process to identify, prevent, mitigate and account for adverse impacts in their operations and supply chain. This includes taking appropriate steps to improve traceability and to verify that raw materials and services are sourced in a legal and responsible manner.

5. RESOURCES, COMPETENCE & AWARENESS

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. DOCUMENTED INFORMATION

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

7. OBJECTIVES & 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. RESILIENCE: PREPAREDNESS & RESPONSE

Suppliers shall have effective business continuity management (BCM), emergency response, and cybersecurity preparedness measures to ensure operations can withstand, respond to, and recover from disruptive events.

9. COMMUNICATION & STAKEHOLDER ENGAGEMENT

Suppliers shall have effective systems to communicate these Principles to all relevant stakeholders, including workers, contractors, suppliers, and local communities. Suppliers shall also establish and maintain a grievance mechanism that is accessible to both internal and external stakeholders, encouraging them to report concerns, illegal activities, or breaches of these Principles without threat of or actual reprisal, intimidation, or harassment.

10. PERFORMANCE EVALUATION & CORRECTIVE ACTION

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

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 & HOUSING

Animals shall be treated humanely with pain and stress minimized. They shall be appropriately housed, enabling species-specific natural behavior.

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. No one below the legal minimum working age – or applicable international standard, whichever is higher – shall be employed. Workers under 18 shall only perform non-hazardous work that does not harm their health, safety, or education, and only if they meet the legal age for employment or have completed 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, or any other characteristics protected under applicable law.

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 ensure transparent and timely communication to workers on how they are compensated, including details of any lawful deductions. 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 planning shall be in place to ensure the safety of the work environment. Safety information related to hazardous materials and other workplace hazards, including pharmaceutical compounds and intermediates, shall be available and used to educate, train workers on hazards. Appropriate equipment, facilities, and services shall be provided to protect worker safety, health, and wellbeing.

Suppliers shall demonstrate good housekeeping practice, provide adequate sanitation and hygiene infrastructure to workers to prevent contamination and manage exposure risks.

Site Leadership and people managers shall visibly demonstrate a culture* of safety.

2. WORKER PROTECTION, HEALTH, AND WELLBEING

Suppliers shall protect workers from over exposure to chemical, psychosocial, biological and physical hazards.

Suppliers shall safeguard total worker wellbeing and industrial hygiene standards by verifying control effectiveness through a combined framework of workplace exposure assessments, monitoring, and proactive medical surveillance.

3. PROCESS SAFETY

Suppliers shall maintain management processes designed to identify, evaluate, and mitigate risks associated with catastrophic events.

Suppliers shall maintain a Process Safety Management (PSM) framework designed to identify, evaluate, and mitigate risks associated with catastrophic events. This specifically includes the loss of containment of hazardous materials (chemical, biological, or high-energy) that could result in severe, large-scale impacts on human health, the environment, or community safety.

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 identified and appropriately managed, controlled, and treated. This includes risks posed by pharmaceuticals into the environment (PiE).

3. CLIMATE CHANGE

Supplier shall monitor and reduce their GHG emissions, establish meaningful targets*, and support their suppliers to do the same.

4. MANAGEMENT OF RESOURCES

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. Suppliers shall evaluate if feedstocks/inputs have significant negative social or environmental impacts. 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]: Due diligence is the process whereby companies identify, prevent, mitigate and account for how they address actual and potential adverse impacts in their own operations, their supply chain and other business relationships.
- 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] OECD Due Diligence Guidance for Responsible Business Conduct
[8] Cambridge Dictionary

- **Greenhouse Gas (GHG) emissions**[9]: Emissions from the seven GHGs covered by the United Nations Framework Convention on Climate Change (Carbon dioxide (CO2); Methane (CH4); Nitrous oxide (N2 O); Hydrofluorocarbons (HFCs); Perfluorocarbons (PFCs); Sulphur hexafluoride (SF6)), and Nitrogen trifluoride (NF3) 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.
- **Targets for carbon emissions reduction**[19]: Meaningful targets adopting the methods set out by the Science-Based Target Initiative (SBTi).

[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
[19] Science Based Targets