



Remedica Limited Third Party Code – Version 1 – Aug 2024

Remedica Limited Third Party Code

Introduction

Remedica Limited (“Remedica”, or, “Company”) is dedicated, amongst others, to the development, production and sale of high quality, safe and efficacious generic pharmaceutical products and is committed to the highest standards of ethics, business conduct, environmental, social and governance. For Remedica, there is an inseparable connection between business success and corporate responsibility to its employees, business partners, society, local communities, and the environment. Remedica’s suppliers and providers (“Associates”) are a fundamental and essential part of the overall success of the Company.

The Remedica Limited Third Party Code (“Code”) outlines the key principles, standards, and behaviours under which Remedica’s Associates are required to operate, reflecting Remedica’s expectations from its Associates, with regards to their production activities and business practices (As per applicability).

The present Code materially incorporates the Pharmaceutical Supply Chain Initiative (PSCI) principles for responsible supply chain management (see <https://pscinitiative.org/principles>).

The Code does not replace local law. Remedica’s expectation from its Associates is for them operate in compliance with applicable laws, rules, and regulations in addition to the principles contained herein.

For the Remedica Limited Third Party Code, the term Associates may also include distributors, wholesalers, licensors, licensees, consignees, other technology partners, and other entities with which the Company interacts and associates with.

Governance and Management Systems

Good governance and management systems are the foundation for compliance with all the PSCI Principles. Associates 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 including also legal compliance. The Governance and Management Systems Principles are:

1. CULTURE, COMMITMENT, AND ACCOUNTABILITY

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



2. LEGAL AND CUSTOMER REQUIREMENTS

Associates shall identify and comply with applicable laws, regulations, recognized standards*, and relevant Company requirements.

3. RISK MANAGEMENT

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

4. TRACEABILITY AND CONTROL

Associates shall have systems in place to carry out due diligence* on their own supply chain and sub-contractors, including but not limited to traceability for the sources of raw materials to support legal and sustainable sourcing.

5. TRAINING AND COMPETENCY

Associates shall have a training program that achieves an appropriate level of knowledge, skills and abilities in management and workers to make sure that they are equipped to live up to the expectations in these Principles.

6. Business Continuity

Associates shall have adequate financial resources to safeguard business continuity and maintain financial stability solvency. Associates are responsible for the development and implementation of appropriate business continuity plans, and, insurances coverages, for their business operations and activities.

7. Audit

Remedica has the right to audit the Associates or assign a third party to ensure the compliance of the Associates in regards to the present Code, ethics, human rights, health and safety, environment, governance and management systems, as also compliance with legal and/or legislative requirements including but not limited to adherence to applicable privacy laws.

8. DOCUMENTATION

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



9. CONTINUOUS IMPROVEMENT

Associates are expected to continuously improve by setting performance objectives and executing implementation plans. Associates shall take necessary corrective actions for deficiencies identified internal or external assessments and/or audits, inspections, and management reviews, including the recording and reporting of near-misses, incidents, and incident prevention opportunities.

10. EMERGENCY PREPAREDNESS AND RESPONSE

Associates shall have effective emergency plans and response procedures.

11. GRIEVANCE MECHANISMS

Associates 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, harassment, or retaliation.

12. RESPONSE AND REMEDIATION

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

13. EFFECTIVE COMMUNICATION

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

Ethics

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

1. PATIENT SAFETY AND ACCESS TO INFORMATION

Associates (as per applicability) 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.



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2. Business Integrity

Associates must not practice or tolerate any form of corruption, extortion, or embezzlement, pay or accept bribes, or other improper payments or be involved in illegal dealings. Suppliers are expected to respect national, European and international laws and regulations, enforced for the prevention of corruption, and comply with sanctions legal framework.

3. ANTI-BRIBERY* AND CORRUPTION*

All forms of corruption* including, bribery*, extortion and embezzlement are prohibited. Associates 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. Associates shall ensure they have adequate systems in place to prevent corruption* and comply with applicable laws.

Associates shall not bribe any public or private person and shall not accept any bribes. No intermediaries, such as agents, advisers, distributors or any other business partners, shall be used to commit acts of bribery.

Facilitation Payments. No facilitation payments are made, irrespective of whether or not local law permits them.

Gifts, Hospitality and Entertainment. Gifts, hospitality and entertainment are never offered, promised or provided with the intent of causing the recipient to do something favouring the Associate and/or Remedica, to reward such behaviour, or to refrain from doing something disadvantaging the Associate and/or Remedica. Gifts, hospitality and entertainment are modest, reasonable and infrequent, so far as any individual recipient is concerned.

Grants, Donations and Sponsoring: Grants and donations are only given if the Associate and/or Remedica do not receive, and are not perceived to receive, any tangible consideration in return. Grants and donations are not perceived to reward any tangible consideration. Sponsoring is not to be used (or perceived to be used) to receive an improper commercial advantage in return. Sponsoring must never reward (or be perceived to reward) an improper commercial advantage.

Political Contributions: If the Associate chooses to make political contributions, they must be made in compliance with all applicable laws, regulations and industry codes and standards, and must not be made with the expectation of direct or immediate return for the Associate or Remedica.

Lobbying: Lobbying is not to be misused for any corrupt or illegal purposes, or to improperly influence any decision.

Public Officials: Any relationship between the Associate and public officials is in strict compliance with the rules and regulations to which they are subject (i.e. any applicable rules or regulations in the particular country relating to public officials or that have been imposed by their employer). Any benefit conveyed to a public official is to be fully transparent, properly documented, and accounted for.



4. FAIR COMPETITION

Associates shall conduct their business consistent with fair and vigorous competition and in compliance with all applicable anti-trust laws. Associates shall employ fair business practices including accurate and truthful advertising. Associates shall comply with all applicable laws regarding trade controls, including anti-boycott laws, economic sanctions, or any type of sanctions, import and customs laws among others.

5. 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.

6. DATA PRIVACY AND SECURITY

Associates shall safeguard and make only proper use of confidential information and personal data to ensure that company, worker, patient, subject*, and donor*, or, customer (as per applicability) privacy rights are protected. Associates shall comply with applicable privacy and data protection laws and ensure the protection, security, and lawful collection, processing and storage of personal data. Associates shall have a GDPR policy (General Data Protection Regulation 2016/679, “GDPR”) which is used to protect all personal data. The use of personal data and sharing of personal data is to take place in strict compliance with the provisions of the GDPR.

Proper Protection of Personal Information: Associates shall have the proper organizational and technical structure, processes and procedures to ensure the protection, confidentiality, integrity and availability of information against accidental, unauthorized or unlawful loss, destruction, alteration, disclosure, use or access.

Proper Security Measures: Associates must have adequate policies and procedures in place which address technical and organizational security and take reasonable steps to stay current, and to confirm on a periodic basis, compliance with those.

Compliance with Cross-Border Transfer Restrictions: Associates must have adequate safeguards, rules and procedures to ensure that they remain in compliance with all applicable laws that govern cross-border data transmissions, where applicable.

Data and/or Information Breach Notification: Associates shall notify Remedica for any suspected or actual data breach concerning the services/deliverables/goods provided. Associates shall appropriately assist Remedica in any investigations in response to a data or information breach.

7. AVOIDANCE AND MANAGEMENT OF CONFLICTS OF INTEREST



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

8. 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

Associates shall be committed to respect the human rights* of internal and external stakeholders* ensuring to treat them with dignity and respect. These Human Rights Principles (as below defined) 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

Associates 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.

Associates must also honor the freedom of association and the effective recognition of the right to collective bargaining, the elimination of all forms of forced and compulsory labor, and the abolition of child labour.

2. CHILD LABOR AND YOUNG WORKERS

Associates shall not use child labour. 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. Supplier should be consistent with ILO's (International Labor Organization) core labour standards and the United Nations Global compact principles, as also, applicable national and European legal framework.

3. NON-DISCRIMINATION

Associates 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.



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4. FAIR TREATMENT

Associates 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

Associates shall pay their personnel according to applicable wage laws and agreed employment contracts, including minimum wages, overtime hours and mandated benefits. Associates shall communicate with the employee 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. Associates are expected to communicate with the employees 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 employees (i.e. social dialogue*) to resolve workplace and compensation issues are encouraged. Associates shall respect the rights of their employees, 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. Employees shall be able to communicate openly with management regarding working conditions without fear of retaliation.

7. LOCAL COMMUNITIES*

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

Health and Safety

Associates shall provide a safe and healthy working environment and support the wellbeing of employees. Health and Safety measures shall extend to contractors and subcontractors on Associates' premises. 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



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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. All process must be performed in accordance with relevant safety standards.

Environment

Associates shall operate in an environmentally responsible and efficient manner to minimize adverse impacts on the environment, and to help their own suppliers/sub-contractors do the same. Associates 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

Associates 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*.

Speak up Channel (aka whistleblowing)

Remedica operates a speak up (aka whistleblowing channel). Remedica encourages its Associates to have the appropriate procedures in place to enable their workforce and partners to report a case of unethical practice or misconduct. Associates can also make use of the speak up channel of Remedica in case they want to report a misconduct that is related or affects Remedica business and supply chain.

Remedica's SPEEKI – Web Portal is available here: <https://portal.speeki.com/>

Should the Associate require any further information and on support in utilizing above platform they can contact Remedica office at info@remedica.com.cy

[Signature Page Follows]



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Confirmation and Execution

I the undersigned, hereby state and confirm that I have read and understood the content of the present Code and adhere and intent to continue to adhere to its contents fully.

I furthermore confirm that I am legally authorized to execute present Code for and on behalf of the below-mentioned Company.

Company Name:

Signature: _____

Name:

Title:

Date:

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).*
- Biodiversity¹: 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.
- Bribery²: 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.
- Circularity³: 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.
- Corruption⁴: The abuse of entrusted power for private gain and / or illicit benefits.
- Culture⁵: Combination of the attitudes, values, and beliefs of an organization that influence how it operates or how it reacts.
- Donor⁶: Any person who donates tissues, cells, organs, and any other body parts for research purposes.
- Due diligence⁷: Research and analysis of a company or organization done in preparation for a business transaction or as part of operational reviews.
- External stakeholder⁸: 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 3 of the PSCI Principles](#)

⁷ [Merriam Webster Dictionary](#)

⁸ [Cambridge Dictionary](#)