We have established an auditing department under the Board to implement ethical management, fulfill supervisory responsibilities, and further optimize internal control and audit processes. The auditing department is headed by a chief auditor who supervises 1 to 2 auditors. The appointment and dismissal of the chief auditor must be approved by the Audit Committee and passed by the Board. The auditing department formulates annual audit plans each year based on current or potential corporate risk issues, and conducts internal audits through general audits, project audits, and subsidiary supervision operations. The chief auditor reports on audit implementations to the Audit Committee and the Board every quarter, and organizes regular independent communications between internal auditors and independent directors to strengthen director supervisor of corporate audits. We also continue to track and re-examine all deficiencies discovered during audits to confirm that related units have adopted timely and appropriate improvement measures. In 2024, the auditing department completed a total of 56 audit reports and discovered no major deficiencies.

The auditing department also reviews appropriateness and implementations of internal controls based on our “Internal Audit System” through audits encompassing all corporate financial, business, operational processes, as well as subsidiaries that comply with regulatory requirements.

Audit management of subsidiaries:

01

The auditing department encourages all subsidiaries to formulate necessary supervision and management control processes and regulations in accordance with local regulatory requirements and actual operational conditions. Internal control regulations should adhere to local laws and regulations for effective management of operational risks

02

We incorporate subsidiaries in internal audits, formulate annual audit plans, and implement subsidiary audits each year based on risk assessments results. In 2024, we issued 10 audit reports for Panco, PharmEssentia USA, and PharmaEssentia Japan; 1 audit report is still being processed. Audited subsidiaries are notified of discoveries and recommendations in all audit reports, and corrections are tracked on a quarterly basis

03

Important subsidiaries undergo at least one on-site audit each year, and subsidiary internal controls and corporate governance are comprehensively assessed through meetings, document reviews, and observations. A total of 4 on-site visits were completed in 2024

04

PharmaEssentia and all subsidiaries conduct at least one self-assessment of internal control systems each year. The auditing department reviews the self-assessment reports of all units and subsidiaries, as well as improvements of internal control deficiencies and abnormalities discovered by the auditing department, to provide a reference for the Board when evaluating the effectiveness of internal control systems and when issuing statements on internal controls

2.2 Business Integrity and Legal Compliance GRI 2-23

PharmaEssentia has designated the general management office as the sole responsible unit (hereinafter "dedicated unit") under the Board and has also provided sufficient resources and appropriate personnel to amend, implement, and interpret the Procedures for Ethical Management and Guidelines for Conduct; provide advisory services; record and file reports; and conduct other monitoring and implementation procedures. The dedicated unit is responsible for the following matters and makes regular reports to the Board each year (at least one report a year):

A. Assisting in incorporating ethics and moral values into the Company's business strategy and adopting appropriate prevention measures against corruption and malfeasance to ensure ethical management in compliance with the requirements of laws and regulations

B. Analyzing and assessing on a regular basis the risk of involvement in unethical conduct within the business scope, accordingly adopting programs to prevent unethical conduct, and setting out in each program the standard operating procedures and conduct guidelines with respect to the Company's operations and business

C Planning the internal organization, structure, and allocation of responsibilities and setting up check-and-balance mechanisms for mutual supervision of business activities within the business scope which are possibly at a higher risk for unethical conduct

D Promoting and coordinating awareness and educational activities with respect to ethics policies

E Developing a whistle-blowing system and ensuring its operating effectiveness

F Assisting the board of directors and management in auditing and assessing whether the prevention measures taken for the purpose of implementing ethical management are operating effectively, and preparing reports on regular assessment of compliance with ethical management in operating procedures

G Preparing and retaining properly documented information such as ethical management policies and compliance statements, situations concerning the performance of undertakings and enforcement, and so on

Ethical Management and Business Codes of Conduct

PharmaEssentia established the Principles of Ethical Corporate Management, Procedures for Ethical Management and Guidelines for Conduct, Codes of Ethical Conduct, and other regulations. These regulations took effect following board approval, and we require the Board and all employees to abide by these rules and regulations to ensure that no unethical incidents occur during operations. PharmaEssentia Japan has established the "Corporate Code of Conduct" to regulate routine employee work behaviors, and has also compiled ethical management and business codes of conduct into a work manual that employees can refer to at any time. Related corporate governance procedures and regulations can be downloaded from our official website.

Our Principles of Ethical Corporate Management contain clear anti-corruption and anti-bribery stipulations, and we regularly educate our employees. In 2024, we required all employees and directors in Taiwan to participate in education and training associated with global codes of conduct encompassing anti-corruption, anti-bribery, and anti-trust/anti-competition matters. Additionally, we also hosted an "Internal material information and prevention of insider trading regulations" course attended by 215 participants, with total training hours amounting to 645 hours. PharmaEssentia USA also disseminated information on regulations associated with business integrity, business conduct, and internal material information protection though code of conduct training and employee manuals. A total of 168 employees participated in training. In 2024, we conducted internal control assessments on anti-corruption and associated risks, and did not discover any anti-competition, anti-trust, and monopoly incidents or conduct. Our "Rules of Procedure for Board of Directors Meetings" contains clear stipulations on how the board should handle conflicts of interest, and we are also planning to establish a Legal Compliance Committee and subordinate ethical management supervision units.

All employees are required to comply with our 7 major business conduct and ethics rules, which stipulate that our personnel should uphold principles of fairness and justice when carrying out their duties, and shall not profit from their positions, or manipulate or misuse information obtained through their roles. Our human resource department has also formulated specific measures for reporting illegal conduct (including corruption) of internal and external personnel. New employees receive training on professional ethics as soon as they join the company. In 2024, PharmaEssentia was not involved in any incidents associated with ethical management and corporate code of conduct violations, and we did not receive any associated grievance reports.

Legal Compliance GRI 2-23

The biopharmaceutical industry is a highly regulated industry. To ensure that PharmaEssentia adheres to global regulations at all stages of drug lifecycles, we referenced domestic and overseas policy and regulation trends to formulate legal compliance strategies and management regulations for global operations. We established a total of 40 regulations, including the "Corporate Governance Code," "Principles of Ethical Corporate Management," "Codes of Ethical Conduct," "Procedures for Ethical Management and Guidelines for Conduct," "Sustainable Development Best Practice Principles," "Operating Procedures for Handling Material Nonpublic Information and Preventing Insider Trading," "Regulations Governing Management and Utilization of Intellectual Property Rights," and "Regulations Governing Management of Litigation Cases/Major Disputes." PharmaEssentia has established a regulatory affairs department, auditing department, corporate governance officer, legal department, human resources department, and other functional departments. We require our colleagues in all associated departments and our suppliers to abide by the aforementioned regulations.

MLR (Medical, Legal, and Regulatory) Committee

MLR is an interdepartmental committee composed of members from the medical affairs, legal, regulatory, and business departments. The MLR Committee is responsible for reviewing and approving all external promotions and communication documents that may be considered drug promotions or product labels by the US FDA, to ensure that the information is scientifically accurate, not misleading, and complies with all internal policies and applicable regulations. The Committee revisits marketing authorizations and adjusts decisions based on the latest laws/regulations and market needs. We sometimes commission external professional institutes to assist with reviewing processes, but supervision and approval procedures are conducted by internal experienced professionals.

In 2024, the Committee recruited new legal/regulatory reviewers, who were selected based on their academic backgrounds and expertise to ensure that they could provide necessary technical and legal recommendations. We often recruit personnel who have served as MLR Committee reviewers at other biotechnology companies so they can use their past experiences as a basis for risk comparisons, enabling effective review and approval while reducing corporate risks.

Summary of Legal Violations GRI 2-27

In 2023, our Zhubei Plant construction site submitted a plan for reducing runoff wastewater. During an on-site inspection, the Department of Environmental Protection discovered that the runoff wastewater treatment facilities were not consistent with the original plan, which constituted a violation of the Water Pollution Control Act, incurring a fine of NT$70,000 in 2024. We and the construction company have already taken measures to address this violation:

Construction company: According to our contract, the construction company is responsible for environmental protection matters during the construction period. In response to the discovered violation, the construction company has already submitted a new runoff wastewater reduction plan, which has been reviewed and approved by the Department of Environmental Protection, ensuring that the procedures comply with related regulatory requirements.

PharmaEssentia: We have directed the construction company to strengthen on-site management measures, increase inspection frequencies, and ensure that wastewater treatment facilities are operating normally. We also strengthened personnel training, established internal monitoring and management mechanisms, and comprehensively strengthened compliance and management capabilities.

Note: All PharmaEssentia sites strictly adhere to regulations set by competent authorities. We have established related internal operational regulations and codes, and we define any legal violation as a "major regulatory violation" which requires immediate improvement and establishment of future prevention measures

Legal Compliance and Specific Actions in Product Lifecycles

SASB HC-BP-270a.1 SASB HC-BP-270a.2

Product Lifecycle Management	Related Regulations	Specific Legal Compliance Actions
Before launch		
New drug R&D and preclinical research	• Good Laboratory Practice (GLP) • Guidelines for safety of nonclinical pharmaceutical trials for animal trials set by the competent authorities in each country	• Established legal compliance regulation section • All functional duties comply with legal regulations • Achieved 100% coverage rate for employee legal compliance training • Established monitoring system for HCP meal expenses • Business regulations and operations for lecture activities • Preclinical ethical guidelines for animal trials • Ethical guidelines for clinical human trials
Clinical trials	• Good Clinical Practice (GCP) • Good Tissue Practice (GTP) • Good Distribution Practice (GDP) • Declaration of Helsinki ethical principles • Regulations set by local competent authorities, such as the "Regulations on Human Trials" and "Pharmaceutical Affairs Act" in Taiwan	
Production and manufacturing	• Good Distribution Practice (GDP) • Good Tissue Practice (GTP) • Good Manufacturing Practice (GMP) • Regulations set by local competent authorities, such as the European Pharmacopoeia, the United States Pharmacopeia, and the "Medical Care Act," "Pharmaceutical Affairs Act," and "Standards for Medicament Factory Establishments" in Taiwan	
Drug registration	• Regulations set by local competent authorities, such as the "Pharmaceutical Affairs Act" and "Regulations for Registration of Medicinal Products" in Taiwan, GMP/GDP regulations for pharmaceutical companies, Common Technical Documents Format, and ICH Guidelines	
Before and after launch		
Protection of intellectual property rights	• United States Patent and Trademark Office, World Intellectual Property Organization, and European Patent Office intellectual property regulations, and patent laws, trademark laws, and other regulations in other countries	• Freedom-to-Operate (FTO) assurance for Group R&D achievements • Aligned with R&D directions and progress, as well as product marketing conditions in different countries, and apply for patents as soon as possible when appropriate • Aligned with drug registration and market launch schedules to register trademarks in different countries as appropriate to comply with the requirements of pharmaceutical supervisory authorities • Keep abreast of market changes, business developments, product usage, innovations, and R&D, as well as feedback on all aspects for continued strengthening of patent and trademark applications • Monitored development progress on similar technologies, products, and trademarks around the world and adopt necessary response measures (such as filing opposition procedures with local trademark offices for similar trademarks in accordance with law)
After launch		
Marketing and sales	• Good Distribution Practice (GDP) • Ethical guidelines set by the WHO and countries around the world	• Implemented transparent reporting mechanisms and ensure that all drug advertisement content passes through MLR reviews • Established monitoring and review system for lecture activities, advisory committees, and HCP meal expenses • Implemented legal compliance review processes and management measures for advisory committees • Other legal compliance policies and standard operating procedures for investigation, monitoring, and employee discipline • Ethical management guidelines for drug marketing • Our Logistics Center obtained a GDP certificate in 2024 (the certificate was extended for the first floor and granted for expansions on the second floor) • In 2024, our subsidiaries in Taiwan continued to align with our parent company in monitoring global drugs and reporting adverse drug reactions and adverse events
Pharmacovigilance	• Good Pharmacovigilance Practice (GVP) • Regulations set by local competent authorities, such as the "Regulations for the Management of Drug Safety Surveillance" and "Regulations for Reporting Serious Adverse Reactions of Medicaments" in Taiwan	