6.2 Legal Compliance and Business Ethics

Material Topic

PharmaEssentia sells its products across Europe, the United States, and Asia. We closely monitor policies and regulations in both Taiwan and abroad, and have developed a global compliance strategy framework for PharmaEssentia's operations. To reduce operational risks caused by non-compliance, the framework is based on four pillars: Structure and Governance, Policy and Action, Operation and Accountability, and Culture and Education.

GRI 3-3

Management Policy

Internal Policies

- Various operation management measures, including Practical Guidelines for Corporate Governance, Guidelines for Business Ethics, Code of Ethics, Operational Procedures and Behavioral Guidelines for Business Ethics, Practical Guidelines for Sustainable Development of Corporate, and Management Procedures for Internal Material Information and Preventing Insider Trading.
- Intellectual Property Management and Utilization Measures
- Lawsuit/Material Dispute Management Measures

External Guidelines

- All business activities and products must comply with the laws and regulations of the relevant regulatory authorities in each country
- The corporate governance evaluation system indicators of the Financial Supervisory Commission

Management Commitment

- Structure and Governance: Establish a global legal compliance plan before and after the launch of products
- Policy and Action: Formulate core legal compliance areas and reasonable policies
- Operations and Accountability: Establish legal compliance operating procedures, fully implement monitoring and accountability management
- Culture and Education: Continuously conduct employee education and promotion to solidify corporate spirit

Accountable Units

- Board of Directors of PharmaEssentia, regulatory affairs unit, legal compliance unit, personnel unit, functional departments, and business and Legal Compliance Functional Teams of each subsidiary
- Various functional departments
- Head of Corporate Governance
- ECCS - Corporate Governance Taskforce

Input Resource

- Implement the ability to prepare financial reports independently and disclose financial information in a timely manner
- Optimize internal controls for litigation-related procedures to track the progress of significant lawsuits through more precise steps and effectively manage content control for formal legal documents
- Each functional department of PharmaEssentia and its subsidiaries shall allocate a budget for the annual legal compliance plan and submit it for approval by the board of directors
- Each functional department shall hire external professional consultants to assist with legal compliance policy projects according to the development needs of the Group

Targets

Short-term Targets for 2023

- Depending on the operational needs, establish a nomination committee to continuously better the mechanism for selecting directors
- Improve the company website to provide direct or synchronized channels for communication or for filing complaints and reports with independent directors (Audit Committee)
- Establish the Guidelines for Practices by Listed Companies for Risk Management in compliance with the law to improve the risk management system
- Strengthen legal compliance management education and training
- Formulate the highest management principle, which is the Code of Business Conduct and Ethical Standards, and related operating policy documents with details for the group
- Include compliance with laws and regulations as an item in the annual audit plan and conduct internal audits regularly
- Actively implement the evaluation indicators of the Financial Supervisory Commission's Corporate Governance 3.0 Sustainable Development Blueprint
- Establish mechanisms and training for due diligence investigation of the adoption of technology of interest
- Strengthen the intensity of contract reviews, and optimize the management process for cases and documents in the legal department

Medium-term Targets for 2024-2026

- Establish a cross-subsidiary legal compliance committee within the group to promote the inclusion of opinions from legal compliance representatives of various functional units in the senior strategic decision-making process, and ensure that operational activities comply with laws and company policies
- Promote the establishment of a global legal compliance committee to oversee the effective implementation of legal compliance plans, and establish a reporting management mechanism for Headquarters and subsidiaries
- Establish an integrity operation supervision unit under the PharmaEssentia's legal compliance committee

Long-term Targets (2026 and beyond)

- Establish a global legal compliance committee
  - Provide a global view of legal compliance risks for each subsidiary
  - Promote cross-regional identification of operational efficiency, and prevent duplicate work
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  - Promote cross-regional identification of operational efficiency, and prevent duplicate work

Handled unexpected incidents properly

Improvement measures were planned, ensuring stable operations within the company

Evaluation of Management Policy

Management Evaluation Mechanism

- Develop relevant measures in accordance with regulatory requirements
- Provide internal audit feedback within the year and report on implementation results to the board of directors on a quarterly basis
- Employee education and training
- Performance evaluation mechanism for directors and managers
- Financial Supervisory Commission's Corporate Governance 3.0 Evaluation System
- Board of directors' performance evaluation by external professional organizations
- Whistleblowing hotline and email

2022 Evaluation Results

- PharmaEssentia has established over 40 operational management measures
- No material violations of ethical and moral standards or any corruption or privacy breaches were found in 2022
- The Internal Auditing Office held four courses on major internal regulations and sustainable governance related to the board of directors
- The legal compliance and HR departments jointly held three courses to further the understanding of code of ethical conduct
- No violations of the operational procedures of the Taiwan Stock Exchange were found in 2022, and there were no cases of Anti-Competitive Behavior and Anti-Trust and Monopoly Practice
- The Articles of Incorporation were amended on May 27, 2022, and the registration of changes was not processed within the legal deadline, resulting in a penalty of NT$30,000 in accordance with Article 387 of the Company Act

Legal Compliance and Stable Operation

GRI 2-27/205-1/205-2/205-3/206-1

The biotech and medical industries are highly regulated due to the significant impact of pharmaceuticals on human life and health. Therefore, we ensure that all business operations and products, from research and development to clinical trials, pharmaceutical manufacturing, drug licenses registration and post-market safety monitoring comply with the regulations of each country we operate in. Our company has been conducting clinical trials in various countries and actively investing in research and development, and we have established a regulatory affairs department and a marketing unit that strictly comply with local pharmaceutical and market regulations. We have also formulated the Intellectual Property Management and Utilization Measures to regulate the acquisition, protection, maintenance and use of our intellectual property. In terms of international arbitration and litigation disputes, we have established the Lawsuit/Material Dispute Management Measures to actively strengthen our control over legal cases and major disputes, and to monitor their progress. In 2022, there were two unexpected incidents, both of which were handled properly, and improvement measures were planned, ensuring stable operations within the company.

Event 1

In 2021, the company was fined NT$1.5 million for violating the regulations on the verification and public handling procedures for important information and the operation procedures for information declaration. Additionally, on April 28, 2022, the Securities and Futures Institute announced that the company was not evaluated for its change in trading company governance evaluation in 2021.

Response and improvement measures>>

The company convened professional legal advisors and accountants to jointly develop specific improvement measures and optimize the system. The existing internal standards and control procedures were made explicit and relevant operational procedures were added. An internal control system improvement plan was also developed and reviewed and confirmed by external lawyers and signing accountants. The company resumed normal trading operations on May 4, 2022, and the company's governance evaluation system for 2022 has also been restored to normal evaluation operations.

Event 2

On May 27, 2022, the company amended its articles of association and was fined NT$30,000 for failing to provide the required documentation for registration within the specified period under Article 387 of the Company Law.

Response and improvement measures>>

The company strengthened personnel education and training to comply with relevant regulatory requirements and meet the processing deadlines.

Standard	Action Plan	Execution in 2022
Anti-Corruption	Focus on prohibiting any form of bribery or improper financial transactions, as well as insider trading, money laundering or illegal political donations, and implementing the company's anti-corruption plan. PharmaEssentia's Headquarters and the US subsidiaries conducted multiple education and training sessions on IRPMA (market marketing regulations) as well as related laws and codes of conduct for clinical and marketing personnel	PharmaEssentia had zero corruption and no illegal political donations
Corporate Social Responsibility	Focus on sponsoring corporate social responsibility activities, including financial activities related to drug donations, research sponsorship programs, and sponsorship or charity activities related to the company	PharmaEssentia had no cases of improper behavior in violating ethical drug marketing standards
Trade Secrets	Trade secrets are important assets of research-based companies and should be actively protected and managed to a degree no less than the protection of intellectual property and patents	PharmaEssentia had no events that harmed customer privacy
Conflicts of Interest	Includes the activities of the company's business operations, which should comply with relevant regulations such as fair-trade law, company law, and securities law, and companies should not engage in unfair competition or monopolies that harm the rights and interests of consumers or other stakeholders. Strengthen the concept of legal compliance among employees to avoid committing violations against Anti-Competitive Behavior and Anti-Trust and Monopoly Practice	PharmaEssentia had zero violations against fair trade, anti-competition, anti-trust, or monopoly regulations

Global Legal Compliance Strategy - US Legal Compliance Column

Establishment of the Legal Compliance Committee and the Legal Compliance Department

No reported complaints / No incidents of violation of Corporate Code of conduct

Conduct multiple legal compliance education and training sessions

100% of employees trained, and 99% signed commitment agreement
100% of relevant vendors trained, and 100% signed commitment agreement

Signed compliance guidelines

Business ethics and legal compliance are regulated

Establishment of multiple complaint channels

Real-time monitoring of regulatory compliance through multiple channels

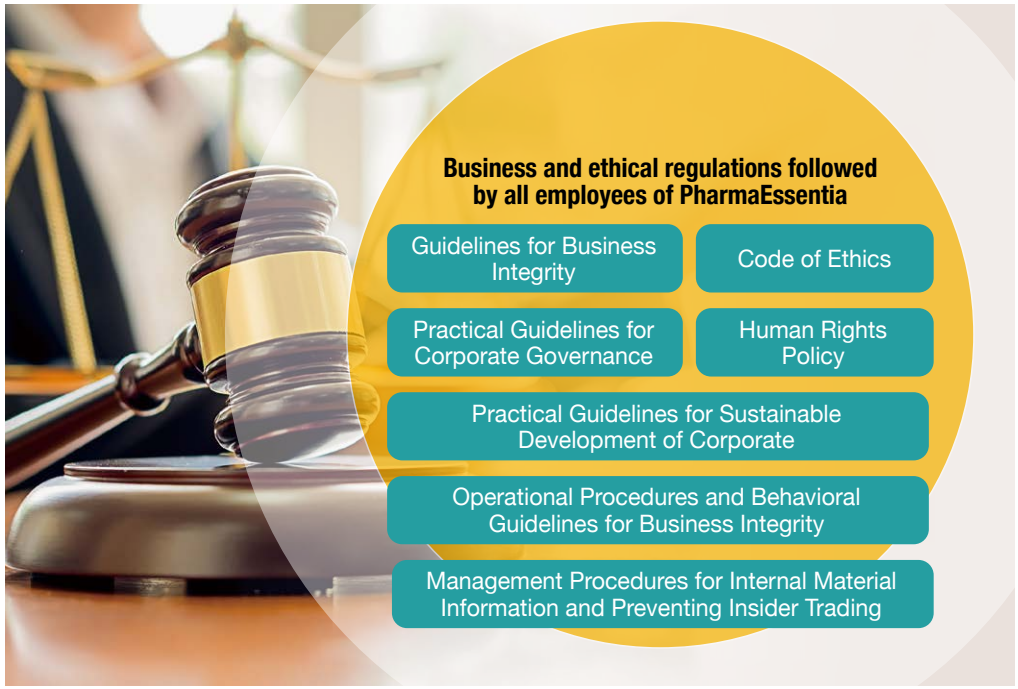
- The US subsidiary is committed to following the highest ethical standards and all applicable laws, regulations, industry standards, company policies, and procedures. The company has established a Legal Compliance Committee and Legal Compliance Department to assist in implementing and strengthening compliance programs related to the US market.
- The Compliance Policy Book-A guide is used to guide and manage business conduct for the US subsidiary. It explicitly specifies regulations related to anti-corruption and bribery, interactions with patients or their representatives, fee-for-service, privacy, and the unique ethical standards of the biopharmaceutical industry. The management policy related to the corporate code of conduct include anti-corruption and bribery, non-discrimination, protection of privacy, conflict of interest prevention, and environmental health and safety.
- Legal compliance education and training are provided, and all employees are required to comply with the rules stipulated in the Policy on Legal Compliance Handbook, with legal compliance evaluated as part of employee performance reviews.
- A whistleblower system and diverse complaint channels have been established, including a website platform (dedicated to employees, anonymous, and handled through a third-party referral process), email, and a hotline number to receive real-time legal compliance-related information. In 2022, there were no violations of ethical business practices and corporate of codes of conduct, and no complaints were received.

Strengthening Ethics and Integrity Policies

GRI2-23/2-24

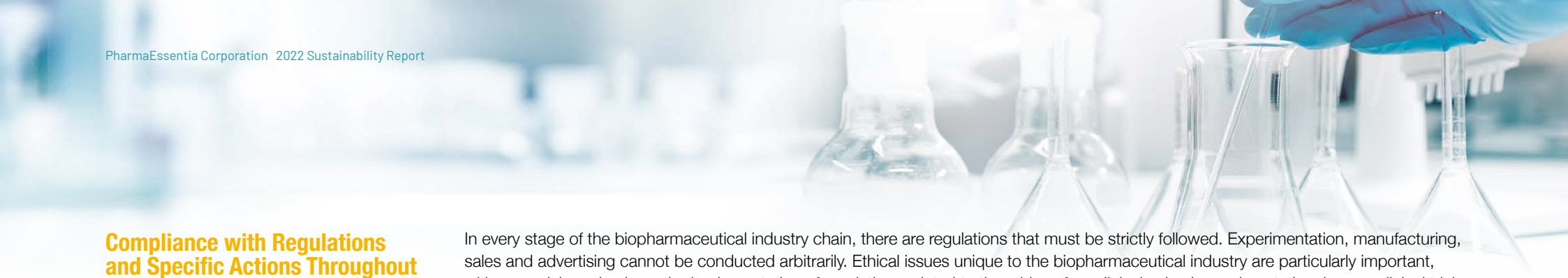
In addition to compliance with laws and regulations, adherence to ethical business practices is even more important. We have established multiple policy commitments to provide employees with a comprehensive framework to follow, and clearly define the responsibilities of each department to ensure the healthy development of organizational operations as well as the implementation of integrity management and supervision. The Board of Directors Meeting Rules further stipulate rules on the board of directors and other relevant conflict of interest. We plan to establish a supervision unit for integrity management under the Legal Compliance Committee in the future to strengthen our management of legal compliance and integrity.

All employees must abide by the 7 business and ethical regulations set by our company. The Human Resources Department will educate new employees on ethical considerations in their work. We have also established a specific reporting system for illegal behaviors (including corruption) for both internal and external personnel. The regulations specify that employees should uphold the principles of fairness and impartiality in their work, and should not use their position for personal gain or manipulate or abuse information obtained through their work. All corporate governance-related procedures and methods can be found in the download section on our company website.



In 2022, we actively solidified our commitment to ethical behavior by:

- We adopted online training courses to enhance knowledge and awareness of ethical concepts and legal risks associated with workplace dishonesty for all employees of PharmEssentia and Panco Healthcare, with a total of 216 participants and a 70.82% attendance rate, as part of our commitment to ethical business practices as an OTC-listed company.
- We conducted two educational training sessions on the IRPMA (Industry Recommended Practices for Market Activities) for clinical and marketing staff, providing clear guidelines to support and execute activities related to product launch, with a total of 20 participants and a 71.43% attendance rate.
- We organized four training sessions for the Internal Auditing Office to prevent the company's directors, managers, or employees from using insider information to buy or sell securities, which included verification and public handling procedures for major announcements, and regulatory education for internal personnel. We also invited external professional institutions to provide courses on the trends and challenges of sustainable corporate governance for all members of the board of directors, executive officers and the Head of Corporate Governance to obtain relevant knowledge.
- In addition, to ensure the comprehensive implementation of ethical business practices, a whistleblowing system to protect whistleblowers and provide a confidential reporting hotline in the local language for suppliers, customers, and other third parties to use is being prepared at our Headquarters. The system will disclose the number and types of reports received and the measures taken, which will help to detect risks, demonstrate our commitment, and protect our reputation.



Compliance with Regulations and Specific Actions Throughout the Product Life Cycle

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

In every stage of the biopharmaceutical industry chain, there are regulations that must be strictly followed. Experimentation, manufacturing, sales and advertising cannot be conducted arbitrarily. Ethical issues unique to the biopharmaceutical industry are particularly important, with a special emphasis on the implementation of regulations related to the ethics of preclinical animal experimentation, human clinical trials and drug marketing throughout the three stages of the product life cycle.

Concrete Actions for Legal Compliance		Pharmaceutical Product Lifecycle	International Local and Internal Ethical Standards
• Establishing a legal compliance department • Setting up an anonymous hotline for reporting violations • Establishing a dedicated section for legal compliance-related measures • Ensuring all functional departments adhere to legal compliance-related measures • 100% coverage of employee training on legal compliance • Monitoring system for meals provided to healthcare professionals • Business rules and operations for speaking events • Ethical guidelines for pre-clinical animal testing • Ethical guidelines for clinical human trials	Before market launch	**New drug development and preclinical research**	✓ Good laboratory practice (GLP) ✓ Non-clinical safety standards for drug testing established by regulatory agencies in each country
		Clinical trials	✓ Good clinical practice (GCP) ✓ Good manufacturing practice (GMP) ✓ Ethical principles of the Helsinki Declaration ✓ Local regulations established by regulatory agencies, such as Taiwan's "Regulations for Human Clinical Trials" and "Pharmaceutical Affairs Act"
		Production and manufacturing	✓ Good distribution practice (GDP) ✓ Good manufacturing practice (GMP) ✓ Local regulations established by regulatory agencies, such as the European Pharmacopoeia, United States Pharmacopeia, Taiwan's "Medical Care Act", "Pharmaceutical Affairs Act", and "Standard for the Establishment of Pharmaceutical Manufacturing Plants"
		Drug registration	✓ Local regulations established by regulatory agencies, such as Taiwan's "Guidelines for Inspection, Registration, and Review of Pharmaceutical Products"
• Implementing a transparent reporting system • Implementing a review process and control measures for speaking events, advisory committees, and the monitoring and auditing system for meals provided to healthcare professionals • Implementing a compliance review process and control measures for advisory committees • Other legal compliance policies and standard operating procedures, such as investigations, monitoring, and employee discipline • Pharmaceutical marketing ethics guidelines	After market launch	**Marketing and sales**	✓ Good distribution practice (GDP) ✓ Relevant ethical regulations established by the World Health Organization (WHO) and regulatory agencies in various countries
		Pharmacovigilance	✓ Good pharmacovigilance practice (GVP) ✓ Local regulations established by regulatory agencies, such as Taiwan's Pharmacovigilance Management Measures

	Applicable ethical guidelines	Our approach	Our goal
Ethical guidelines for preclinical animal experiments	• ICH guideline "Non-Clinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals", as well as country-specific regulations such as "Non-Clinical Safety Guidelines for Drugs" • GLP	• Establishment of an Institutional Animal Care and Use Committee (IACUC) to review and oversee animal experiments and animal care in our institution • Outsourcing of animal experiments to Contract Research Organizations (CROs) that have obtained GLP certification, both domestically and internationally • Use of healthy, infection-free experimental animals of Specific Pathogen Free (SPF) level to prevent interference from specific diseases in the test results • Actively implementing the 3R principles for experimental animals: "Replacement", "Reduction", and "Refinement"	To ensure that researchers in animal experiments comply with relevant legal requirements and minimize the use of experimental animals as much as possible.
Clinical Trial Ethics for Human Subjects	• Internal policies on clinical trials • The Helsinki Declaration • GCP (Good Clinical Practice) • Trial protocol and local regulations	• Standard operating procedures for the development and approval of trial protocols and informed consent forms for participants • All trial protocols and informed consent forms must be reviewed and approved by the health authorities and the Institutional Review Board (IRB) before the trial begins • Participants in clinical trials led by PharmaEssentia will be insured with clinical trial insurance to protect their personal rights and interests • During the trial, the personal information and privacy of participants will be protected • Regular monitoring and auditing will be conducted during the trial	Ensuring the safety, privacy, and rights of clinical trial participants demonstrates that PharmaEssentia is a trustworthy Biopharmaceutical company that patients can rely on.
Ethics in pharmaceutical marketing	• World Health Organization (WHO) • Pharmaceutical Research and Manufacturers of America (PhRMA) • International Research-Based Pharmaceutical Manufacturers Association (IRPMA) • National Council for Prescription Drug Programs (NCPDP) • Ethics guidelines set forth by the Foreign Corrupt Practices Act (FCPA) • Internal policies such as "HCP & HCO Interaction Policy" and "Promotional Material Policy"	• All employees must follow the ethical standards set forth by the aforementioned organizations when interacting with healthcare-related individuals or organizations • Marketing activities must be transparent, ethical, accurate, and balanced, with no misleading information • Marketing materials must contain correct assessments of product risks and benefits, as well as appropriate usage information • Products may not be marketed under the guise of human research studies	We ensure that healthcare professionals receive necessary information and that patient care and welfare are protected in an ethical manner, in line with our mission and responsibilities. In 2022, there were no incidents of quota errors related to marketing.