2 Corporate Governance

Chapter Highlights

0 Violations	No breaches of Business Integrity and Code of Conduct
100%	Attendance Rate by Board of Directors and Compensation Committee
2	Female Directors
92	Valid Patents, 118 Valid Trademarks
4	R&D IP Education and Training Sessions
53	R&D IP Education and Training Hours
100%	Audit Findings Resolution Rate
0	Data Security Breaches

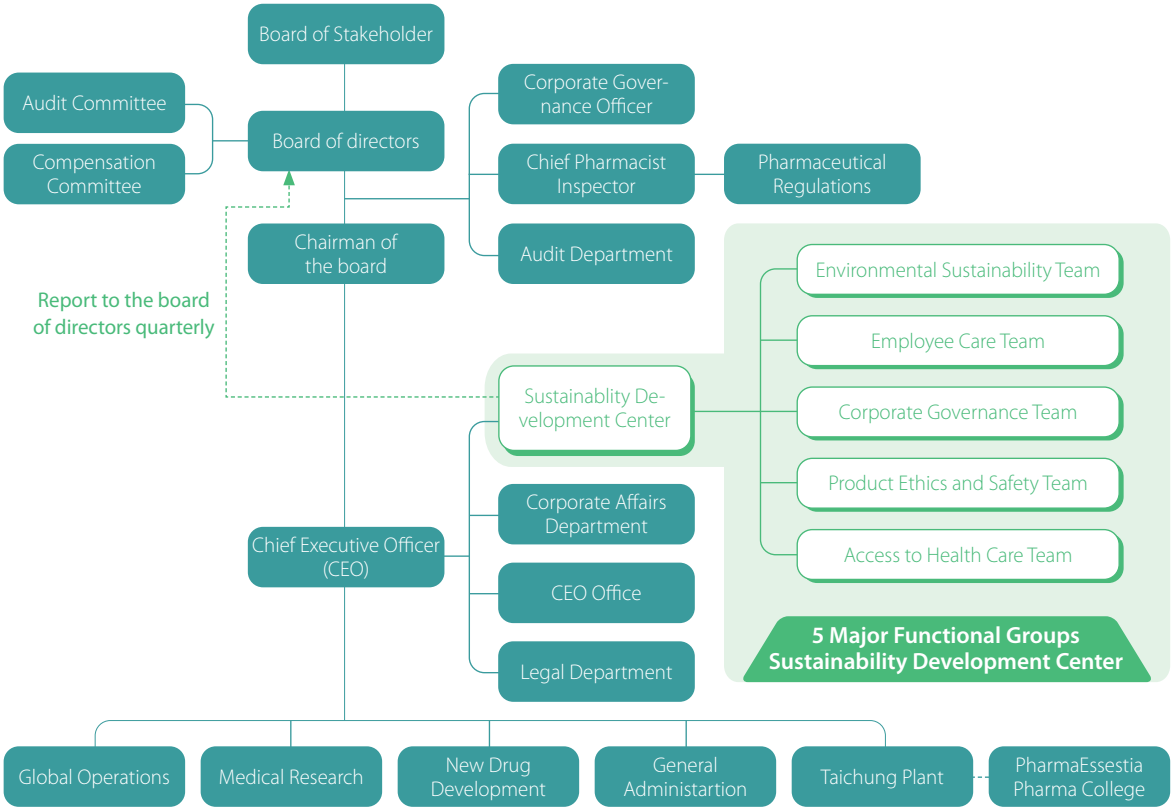
PharmaEssentia highly values regulatory compliance, continuously enhancing the functions of the Board of Directors from a governance perspective, implementing policies on integrity in business, risk management, and information security management. These initiatives are aimed at enhancing corporate resilience and operational capabilities, continually achieving new heights in operational performance.

2.1 Corporate Governance Framework

Board Selection and Responsibilities

GRI 2-9, 2-10, 2-11, 2-15

PharmaEssentia's Board of Directors is the highest governance body, operating under a unitary board system with a term of three years; the most recent term spans from August 5, 2021, to August 4, 2024. The Board's responsibilities include formulating the company's sustainability strategy, overseeing management, and holding significant accountability to the company and its shareholders. The Board oversees committees such as the Audit Committee and the Compensation Committee. The Sustainable Development Center is directly under the CEO, and its functions are shown in the figure on the right.



100%

Attendance Rate by Board of Directors and Compensation Committee

Functional Committees GRI 2-20

PharmaEssentia's Board of Directors has established two functional committees: the Audit Committee and the Remuneration Committee. These committees are composed entirely of independent directors. The Remuneration Committee includes one external expert, Professor MingChuan Hsieh, further strengthening the Board's functionality and enhancing management mechanisms.

Committee	Audit Committee	Remuneration Committee
Responsibilities	Assists the Board of Directors in fulfilling their oversight role regarding the company's accounting, auditing, financial reporting processes, and the integrity and quality of the company's financial controls. Additionally, the committee oversees the management and control of existing or potential issues that could impact the company, thereby strengthening internal control mechanisms.	Assists the Board of Directors in establishing and reviewing policies, systems, standards, and structures for the performance evaluation and remuneration of directors, supervisors, and managers.
Composition	Independent Director: JinnDer Chang Independent Director: Patrick Y. Yang Independent Director: JienHeh Tien	Independent Director: JinnDer Chang Independent Director: Patrick Y. Yang Independent Director: JienHeh Tien Professor Ming-Chuan Hsieh
Number of Meetings	13	3
Attendance Rate	100%	100%

Avoiding Conflicts of Interest GRI 2-15

The company has established several policies including "Board Meeting Rules," "Code of Business Integrity," and "Operating Procedures and Guidelines for Business Integrity" to ensure that the nomination process for board members adheres to government regulations and avoids any improper benefits that could arise from the official capacities of the company's directors and staff. Currently, no board members have significant conflicts of interest, and there is no single shareholder with absolute control: The company's founder and their family members hold less than 5% of the shares; government shareholding mainly comes from the National Development Fund Management Committee of the Executive Yuan and the Committee of Yaohua Glass Corporation, together holding approximately 9.33% of the shares, with no special stock arrangements. For more details, please refer to the company's annual report.

Board member selection is conducted by the shareholder meeting based on the Director Election Policy, taking into account the company's size and the shareholding pattern of major shareholders as well as practical operational needs. The company has a "Diversity Policy for Board Members," ensuring that board members have diverse professional and industry backgrounds, providing expertise in operational judgment, accounting and analysis, business management, industry knowledge, response to climate change, and international market perspectives.

Board Composition and Diversity

GRI 2-9, 2-10, 2-11, 2-15, 405-1

PharmaEssentia's Board of Directors comprises 11 members, with an average tenure of 8.3 years. The board includes two female directors, representing 18% of the board composition. There are three independent directors, accounting for 27.2% of the total board members. Plans are in place to potentially increase the number of female directors and independent directors to more than one-third, depending on operational needs of the company. The composition of the Board of Directors is as follows:

Names	Nationality	Expertise and Skills	Gender	Professional Competencies								Age Group			Tenure of Independent Director			Dual Role as Senior Executive (Yes = O)
				Operational Judgment	Accounting / Financial Analysis	Business Management	Crisis Management	Industry Knowledge	Global Market Perspective	Leadership	Decision-making	60 Years & Below	60-69 Years	70 Years & Above	7-9 Years	4-6 Years	1-3 Years	
ChingLeou Teng	R.O.C.	Biotechnology	Female	✓		✓	✓	✓	✓	✓	✓			O				O
KoChung Lin	R.O.C.	Biotechnology	Male	✓		✓	✓	✓	✓	✓	✓			O				O
ShenYou Gong	R.O.C.	Financial Services	Male	✓	✓	✓	✓		✓	✓	✓		O					
BenYuan Chen	R.O.C.	Education	Male	✓		✓				✓	✓			O				
YenChign Hwang	R.O.C.	Financial Services	Female	✓	✓				✓		✓	O						
Chao Chung Kuo	R.O.C.	Water Resources	Male	✓		✓	✓	✓	✓	✓	✓	O						
ChanKou Hwang	R.O.C.	Biotechnology	Male	✓		✓	✓	✓	✓	✓	✓		O					O
ShenYi Li	R.O.C.	Law	Male	✓				✓	✓		✓			O				
JinnDer Chang	R.O.C.	Accounting Law	Male	✓	✓	✓	✓		✓	✓	✓			O	O			
Patrick Y. Yang	USA	Biotechnology	Male	✓		✓	✓	✓	✓	✓	✓			O	O			
JienHeh Tien	R.O.C.	Biotechnology	Male	✓		✓	✓	✓	✓	✓	✓			O		O		

Continued Enhancement of Board Knowledge

GRI 2-17

To strengthen board functionality, the company offers a variety of continuing education courses for board members. In 2023, all 11 board members met regulatory requirements for training, participating in a total of 9 sessions and accumulating 81 person-hours of training. The courses covered the following topics:

- ◆ Information Security and Technology Management: 3 sessions, totaling 63 person-hours.
- ◆ Corporate Governance Practices: 3 sessions, totaling 9 person-hours.
- ◆ Climate Change and Carbon Management: 2 sessions, totaling 6 person-hours.
- ◆ Financial Reporting and Management Analysis: 1 session, totaling 3 person-hours.

For more detailed information, please refer to the directors' training link: https://mops.twse.com.tw/mops/web/t93sc03_1

Board Performance Evaluation GRI 2-18

PharmaEssentia has established the "Board Performance Evaluation Policy" and the practices for "Board Self-Assessment or Peer Evaluation" to set performance goals and assessment systems for the board. An internal evaluation of the board's performance is conducted at least once annually, with an external professional independent organization appointed every three years to perform the annual board performance evaluation. The results of the 2023 internal evaluation of the board and its members were reported to the board on February 26, 2024, in accordance with the law. The assessment was unanimously approved with no further recommendations.

For external evaluations, the most recent was conducted by the Taiwan Corporate Governance Association for the period from November 1, 2020, to October 31, 2021 (the evaluation report can be accessed on the website). The evaluation recommended four improvements, including strengthening the director nomination process, developing a comprehensive management talent cultivation plan, establishing a robust whistleblower mechanism and communication channels, and creating a dedicated corporate governance section on the company's official website. In response, PharmaEssentia has set up a corporate governance section on its official website; in 2023, the focus was on recruiting senior management talent for international expansion plans. The Taiwan headquarters will also initiate training programs for key personnel at all levels in 2024, with implementation following board approval according to the set program goals and internal approval authority.

Linking Director Remuneration Policy to Sustainable Performance GRI 2-19, 2-20

The remuneration for our company's directors is determined according to internal statutes, with an allocation not exceeding 5% of the profit remaining after offsetting accumulated losses for the year. Directors' compensation is based on their involvement in company operations, performance contributions, and results from board performance evaluations. Information regarding the remuneration of directors and senior management can be referred to in the annual report. We are in the process of revising the director remuneration policy for the next board election to align it with the company's sustainability goals and performance indicators.

The performance indicators for the Chairwoman, CEO, and General Manager are linked to sustainable development activities. Key performance indicators (KPIs) include ongoing investment in the innovation of new drugs, driving key global clinical trials, accelerating drug licensing applications, deepening global business operations, successfully scaling up commercial production and improving process efficiency, optimizing the global supply chain and transportation efficiency, enhancing the global digital systems operations, and fulfilling corporate social responsibility.

Participation in Professional Associations GRI 2-28

PharmaEssentia chooses to engage with biotech and pharmaceutical associations, maintaining membership through the payment of dues. We collaborate with these associations to extend our influence and promote industry development.

2023 Participation in External Associations	Annual Membership Fees (NTD)
Taiwan Research-based Biopharmaceutical Manufacturers Association	300,000
Taiwan Pharmaceutical Manufacturer's Association	120,000
Development Center for Biotechnology (Non-profit Organization)	76,190
Taipei Pharmaceutical Business Association	34,400
The Allied Association For Science Park Industries, Taiwan	72,000
Taiwan Pharmaceutical Manufacture and Development Association	50,000
Taiwan Bio Industry Organization	20,000
Hematology Society of Taiwan	50,000
Taiwan Parenteral Drug Association	7,000
Chinese Association for Pharmaceutical Agents	32,000
Institute for Biotechnology and Medicine Industry	20,000
Taiwan Myeloproliferative Neoplasms Association	50,000
Total	831,590

Tax Strategy and Governance

GRI 207-1, 207-2, 207-3, 207-4

PharmaEssentia has established a tax policy and commitment; the company rigorously operates in accordance with the tax laws of Taiwan and each market where it operates, and ensures transparency in reporting to strengthen compliance with tax laws and commitments across the group. The responsibility for tax management within the company rests with the Head Office's Accounting Department, which coordinates with the accounting departments of the subsidiaries to plan and legally manage tax filings.

PharmaEssentia is committed to following tax management guidelines to reduce tax risks, optimize post-tax operational results, and protect shareholder interests:

PharmaEssentia Tax Policy and Commitments

1. Compliance with Tax Laws and Regulations: All operations are conducted in accordance with relevant tax laws and regulations.
2. Arm's Length Principle: Transactions between related entities are conducted based on the arm's length principle, adhering to the internationally recognized transfer pricing guidelines published by the Organisation for Economic Co-operation and Development (OECD).
3. Transparency in Financial Reporting: Financial reports are transparent, and tax disclosures comply with relevant regulations and standards.
4. Prohibition of Tax Avoidance Transactions: Engages in no transactions that are solely for the purpose of tax avoidance.
5. Mutual Respect and Transparency with Tax Authorities: Establishes a relationship of mutual respect and transparency with tax authorities.
6. Tax Impact Consideration in Decision Making: Major company decisions consider the impact of taxes.
7. Tax Risk Assessment: Analyzes the operating environment and utilizes management mechanisms to assess tax risks.
8. Enhancing Tax Expertise: Strengthens tax expertise through ongoing training and development of personnel.

For the year 2023, the company recognized an income tax expense in the profit or loss statement. Please refer to the table below for the reconciliation of income tax expense to the accounting profit multiplied by the applicable tax rate.

Reconciliation of Income Tax Expense to Accounting Profit Multiplied by the Applicable Tax Rate

(Unit: NTD '000)	2021	2022	2023
Profit Before Tax from Continuing Operations	$(2,810,988)	$(1,841,871)	$(986,934)
Income Tax Calculated at the Parent Company's Statutory Rate	$(562,198)	$(368,374)	$(197,388)
Tax Impact of Deferred Tax Assets/Liabilities	562,198	(68,107)	(168,670)
Other	-	(30,580)	2,959
Total Income Tax Expense Recognized in Profit or Loss	$0	$(467,061)	$(363,099)

Source: For detailed information, refer to the company's annually audited consolidated financial statements.

Internal Control and Internal Audit

To assist the Board of Directors and management in implementing corporate governance and strengthening internal control and audit functions, our company's Internal Audit Department reports directly to the Board of Directors. The department is headed by a Chief Auditor, with one to two auditors under Chief Auditor supervision. The appointment and dismissal of the Chief Auditor must be approved by the Audit Committee and passed by the Board of Directors.

The Chief Auditor reports to the Audit Committee and the Board of Directors quarterly on the execution of audit tasks, enhancing the Board's oversight of the implementation of the company's audit system. Regular meetings are scheduled for independent communication between internal auditors and independent directors. Furthermore, any deficiencies identified during the annual audit plan's internal control checks are continuously monitored and re-evaluated to ensure that the relevant units have taken timely and appropriate corrective actions.

Routine and project-specific audits, along with subsidiary oversight tasks, are conducted to assess the functionality of internal controls and identify potential risks. These efforts assist the Board of Directors and management in fulfilling their responsibilities. In the year 2023, the audit unit completed 55 audit reports without identifying any significant deficiencies.

2.2 Business Integrity and Code of Conduct

PharmaEssentia's Commitment:

From the Board of Directors to all employees, PharmaEssentia adheres strictly to the Business Integrity and Code of Conduct. All company governance-related procedures can be accessed and downloaded from the company's website.

Anti-Corruption and Anti-Bribery Measures:

PharmaEssentia has established clear policies against corruption and bribery and regularly conducts training and educational sessions for all employees and directors. In 2023, the company provided training on anti-corruption, anti-bribery, and anti-trust/anti-competitive practices. An internal control system assessment related to corruption risks conducted in 2023 revealed no corrupt activities within operational practices, and there were no incidents of corruption, anti-competitive, anti-trust, or monopolistic behaviors reported.

Board of Directors Meeting Rules:

The rules specify systems for avoiding conflicts of interest among the Board of Directors and other relevant parties. Future plans include establishing a monitoring unit under the Compliance Committee.

Employee Compliance:

All employees are required to follow seven major business conduct and ethics rules, which ensure that company personnel adhere to principles of fairness and justice in their professional duties, prohibiting profit-making from their positions or the manipulation and misuse of information obtained through their roles. The Human Resources department has established a specific reporting system for illegal activities, including corruption, by both internal and external personnel. New employees receive training on professional ethics as soon as they join the company.

In 2023, PharmaEssentia did not have any violation cases of ethical management and corporate code of conduct, nor did it receive any complaints.

0 Violations

No breaches of Business Ethics and Integrity Code of Conduct

2023 Initiatives:

Integrity Management Code

In 2023, the company invited the Securities and Futures Institute to conduct online training for employees, focusing on preventing insider trading and compliance with related laws. Four educational sessions were held, with a total of 186 participants and 372 training hours.

Business Ethics and Compliance Standards

To enhance awareness and understanding of pharmaceutical safety monitoring and compliance among all employees, the company's Drug Safety Monitoring Unit organizes mandatory training sessions at least once a year. In 2023, online training and feedback via questionnaires were conducted for employees at the Taiwan headquarters and subsidiary Panco, with a total of 311 participants and 155.5 training hours.

Internal Information and Insider Trading Prevention

The Audit/Legal Department organized three sessions in 2023 to educate directors, managers, employees, and subsidiary managers about regulations concerning significant information and short-term insider trading. These included online sessions and external professional presentations on current applications, opportunities, and future challenges of artificial intelligence to enhance their knowledge. A total of 42 participants attended, with 99 training hours.

2.3 Risk Management

Risk Governance Unit:

The Board of Directors serves as the highest supervisory and decision-making body for risk management, endorsing the overall objectives and policies for risk management and continuously overseeing the effective operation of risk management mechanisms. The Audit Committee, the Audit Office, and the Corporate Governance Director are established under the Board to manage both existing and potential risks, thereby strengthening internal control mechanisms to reduce risks, proactively mitigate negative impacts, and prevent financial losses.

Risk Management Policies and Practices:

The company has established internal risk management policies, procedures, and control systems in accordance with relevant standards, managing all risk issues, impacts, and corresponding significant topics properly. Annually, the overall risk management objectives and policies are ratified by the Board of Directors. Board of Directors assigns the senior management responsible for the major issues management and continues to ensure the effective operation of the risk management mechanisms through the regular supervision.

Risk Identification and Classification:

PharmaEssentia adopts the 2018 COSO Enterprise Risk Management (ERM) framework, along with the biotech industry-specific requirements, to classify risks into nine categories. For each category of risk, different mitigation strategies are employed to reduce their impact on the company.

Risk Category	Definition	Mitigation Strategy
Industry Risk	High-risk industry due to the high investment and uncertainty in drug development timelines.	• Besremi is already on the market; ongoing development using PEGylation technology platform to develop other long-acting protein drugs, expanding new indications to maximize R&D efficiency, and reducing single product market risk.
Market Risk	New drug development is time-consuming and has a low success rate. If successful, the product must compete with existing or alternative products.	• Develop new products focusing on orphan drugs, which typically have fast-track review benefits, potential for free pricing, and market exclusivity upon market entry. • Collaborate with external companies to diversify product offerings.
R&D Risk	Includes risks from clinical trial progress or results differing from expectations, competitors' advancements, difficulty in retaining/ developing R&D talent, and heavy reliance on CRO/CMO.	• Develop drugs for various indications to diversify risk. • Recruit biotech industry talent to create and maintain conducive R&D environment. • Select cooperative trial organizations to foster long-term partnerships.
Financial Risk	Risks involving exchange rates, inflation, R&D investments, and operational capital requirements causing financial losses.	• Financial unit interacts closely with forex banks, monitors market trends, and strictly manages financial resources and budget execution.

Risk Category	Definition	Mitigation Strategy
Legal Risk	Risks from international arbitration that could lead to reputational damage or financial loss.	• Engage a professional legal team to handle international arbitration issues to protect and maximize shareholder interests.
Policy Risk	Risks from geopolitical situations or changes in national policies.	• Stay updated with international political and economic news, monitor impacts on production supply chains, and adjust business strategies swiftly. • Establish a regulatory affairs department to keep track of drug approvals and changes in health insurance policies.
Technology Change Risk	Risks including information security, digital transformation, talent skills, supply chain disruptions, or regulatory changes affecting operations.	• Establish an information security management team responsible for promoting, governing, and monitoring information security, continually strengthening information security management to protect trade business secrets and stakeholder interests.
Environmental Risk	Risks from climate change, natural disasters, or pandemics.	• Implement the TCFD framework to enhance climate risk management, pass ISO 14064-1 inspections at Taichung plant, and implement various energy-saving and carbon-reduction measures. • Strengthen SCM to maintain safety stock and develop alternative material sources.
Other Risks	Risks not categorized above that could cause significant losses.	• Implement corresponding emergency measures based on the severity of the situation.

Remediation of Negative Impacts GRI 2-25, 2-26

The company has established a comprehensive remediation process for negative impacts, structured in three phases: prevention, grievance, and corrective action. This approach ensures effective responses to both potential and emergent issues.

1. Prevention

Strict Policy Formulation

Implementing detailed policies requiring employees and suppliers to strictly adhere to standards related to business integrity, pharmaceutical marketing ethics, human rights, and environmental protection to prevent any violations.

Robust Information Security Control

Enforcing stringent information security management and control measures to ensure data security and protect privacy rights.

Comprehensive Risk Management

Utilizing the COSO ERM framework to perform thorough assessments coupled with conducting numerous educational trainings to ensure all employees are aware of the preventive measures against risks.

2. Establishment of Grievance Mechanisms

Multiple Internal and External Reporting and Grievance Channels
(Create diversified two-way communication channels for colleagues and listen to the voices of employees)

Internal Communication Channels

- Labor-management meetings
- Welfare committee meetings
- Employee suggestion e-mail box: voice@pharmaessentia.com

External Grievance Channels

- ESG dedicated web portal for disclosures and contact: includes updates, downloads, newsletters, interactive sections, and contact information.
- Reporting of workplace legal violations: hr@pharmaessentia.com

3. Review and Improvement

Case Handling: Complaint cases are forwarded by the receiving units to the responsible departments based on the nature of the issues. Proposed corrective measures are discussed with employees or external stakeholders.

Documentation and Compliance: The audit office maintains records of the outcomes to ensure compliance and reasonableness. These are disclosed timely in the sustainability report to enable stakeholders to have complete access to the company's information.

2.4 Compliance with Laws and Regulations GRI 2-27

The biotech and medical industry is subject to stringent regulatory oversight. To ensure that PharmaEssentia complies with global regulatory standards throughout the drug lifecycle, the company keeps abreast of domestic and international policy and legislative developments to formulate its global compliance strategies.

PharmaEssentia has established various operational management procedures to ensure compliance, including:

- Corporate Governance Practices Code
- Business Integrity Code
- Code of Ethical Conduct
- Business Integrity Operating Procedures and Behavior Guidelines
- Sustainable Development Practices Code
- Internal Significant Information Management and Insider Trading Prevention Procedures
- Intellectual Property Rights Management and Utilization Procedures
- Litigation and Major Dispute Management Procedures

In total, over 40 procedures have been established to govern operations. Compliance units within PharmaEssentia such as the Regulatory Affairs unit, Audit Office, Corporate Governance Director, Legal Department, Human Resources, and other functional departments enforce these procedures and require adherence by all relevant internal teams and suppliers.

Regulatory Compliance During Product Lifecycle: SASB HC-BP-270a.1, HC-BP-270a.2

Concrete Actions for Legal Compliance	Pharmaceutical Product Lifecycle	International Local and Internal Ethical Standards
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	• Establishing a legal compliance committee • 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
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 mannufacturing	✓ Good distribution parctice (GDP) ✓ Good manufacturing practice (GMP) ✓ Local regulations established by regulatory agencies, such as the European Pharmacopoeia, United States Pharmacopeia, Tawan'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, Registartion, and Review of Pharmaceutical Products"	
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	• Implementing a transparent reporting system • Implementing a review proess 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
Pharmacovigilance	✓ Good pharmacovigilance practice (GVP) ✓ Local regulations established by regulatory agencies, such as Taiwan's Pharmacovigilance Management Measures	

Regulatory Compliance Incident Description, Subsequent Handling, and Prevention Measures GRI 2-27

In 2023, our company faced one compliance violation. In November, an excess purchase of 3,000 shares of treasury stocks resulted in a penalty of NT$300,000 imposed by the Financial Supervisory Commission. The company has duly addressed this issue in accordance with relevant laws governing the repurchase of treasury stocks and has planned corrective measures.

Incident Description

The Board of Directors of our company passed a resolution on July 28, 2023, to repurchase treasury stocks, intending to buy back 4,000,000 shares but turn out to be 4,003,000 shares. Due to an oversight by the personnel in charge of executing the repurchase, 3,000 shares were bought in excess, violating Article 28-2, Paragraph 3 of the Securities and Exchange Act. Consequently, the Financial Supervisory Commission imposed a fine of NT$300,000. Following the directive under the sanction letter no. 11203575891 from the Securities and Futures Bureau, the company disposed of these 3,000 treasury shares on December 20, 2023, and submitted the proceeds from this disposal. As of now, there have been no similar incidents. Furthermore, the company has established an internal review mechanism for personnel and enhanced training programs to ensure compliance with domestic laws and regulations.

2.5 Data Security and Privacy Protection

Strengthening of Information Security Measures:

In 2022, to enhance our information security defenses and management mechanisms, and to comply with the "Guidelines on the Establishment of Internal Control Systems by Publicly Listed Companies," PharmaEssentia announced on the website that it amended its "Information Security Management Procedures." Additionally, established a Cybersecurity Promotion Team, responsible for driving, coordinating, supervising, and reviewing matters related to information security management. The information security officer reports annually to the Board of Directors, with the most recent report completed on December 26, 2023.

Implementation and Certification of ISO 27001:

In October 2023, PharmaEssentia implemented the ISO 27001 Information Security Management System and anticipates receiving third-party certification by June 2024. To enhance the information security awareness of all employees, the company conducted a social engineering training session and two educational sessions focused on ISO 27001 in 2023, involving a total of 271 participants and approximately 323.5 hours. Additionally, one employee undertook a 40-hour course to become a Lead Auditor for ISO/IEC 27001:2022, and has since obtained the certification. Plans are underway to replicate these management practices in subsidiaries in the United States and Japan, starting with the Taiwan production site, and to continue their maintenance and operation.

Data Security Initiatives in the United States:

While PharmaEssentia USA has not implemented the ISO 27001 Information Security Management System, it has initiated cybersecurity training programs. All employees are required to regularly complete these training sessions to enhance their security awareness. In 2023, ten draft policy documents related to information security were created, which are to be confirmed and implemented by the management in 2024.

Information Security Management Activities and Actions at Headquarters

Initiatives & Roadmap

2023 Performance

- Data Loss Prevention (DLP) End-Point Security Protection
- Quality Assurance Department Document Encryption (Phase One)
- EDR Deep Learning Threat Detection and Protection Software
- Zero Trust Network Architecture Optimization & Access Services
- Email Archiving
- Patching High-Risk Vulnerabilities and Annual Cybersecurity Social Engineering Drills
- ISO 27001:2022 Information Security Certification Guidance

2024 Short-Term Goals

- Obtaining ISO 27001 Certification
- Implementation of a SIEM (Security Information and Event Management) System

2025-2030 Medium to Long-Term Goals

- Planning and Implementation of a Data Management Platform (DMP) for File Encryption.
- Zero Trust Cybersecurity: Integrated System and Network Defense with Proactive Alert Mechanisms.
- Continuous System Operations, Disaster Recovery (DR) Backup Planning and Implementation.

Implementation of Customer Privacy Protection GRI418-1

Scope of Information Security and Privacy Protection:

In addition to our internal employees, the scope of our information security and privacy protection efforts extends to healthcare professionals, medical institutions, outsourced partners, and clinical trial participants.

Patient Information Security:

All external research organizations working with PharmaEssentia and medical staff involved in clinical trials at hospital sites are required to strictly adhere to our privacy protection policies. They must also comply with various national and international regulations, such as the European Union's General Data Protection Regulation (GDPR), Good Clinical Practice (GCP) guidelines, the Declaration of Helsinki, Taiwan's Human Research Ethics Policy Guidelines, and the Medical Act. These measures are part of our commitment to ensuring the protection of personal data. In 2023, there were no incidents of employee or customer data protection and privacy complaints, nor were there any complaints regarding the loss of customer data across all PharmaEssentia

2.6 Intellectual Property Management

PharmaEssentia has established "Intellectual Property Management and Utilization Procedures" to regulate the acquisition, protection, maintenance, and utilization of the company's intellectual property rights. From a legal perspective, the company has set "Litigation and Significant Dispute Management Procedures" to regulate the control of legal cases and significant disputes. Each year, the Intellectual Property Department regularly reports to the Board of Directors on the execution of the previous year's intellectual property management plan and the plan for the upcoming year.

The execution of the 2023 intellectual property management plan and the new plan for 2024 were reported to the Board of Directors on February 26, 2024, ensuring the effective management and protection of the company's intellectual property rights. The Board's full awareness assists the company in enhancing its intellectual property strategy and protection, moving towards greater refinement.

Patent Structuring and Strategy

The decision to file a patent application for a research and development result, and the regions/countries in which to apply, must be made according to PharmaEssentia procedures, handled on a case-by-case basis. With the different indications/patient types/market conditions of Besremi and other new drugs developed by PharmaEssentia, the demand for patent applications and the countries of application will also change. The company considers various factors including marketing, manufacturing, local health insurance reimbursement statuses, availability, and regulatory requirements before making decision on the patent application.

Practices in Intellectual Property Rights at PharmaEssentia include:

1. Continual Patent Applications and Acquisition Worldwide:

PharmaEssentia places great importance on patent protection and management, respecting global patent protections and intellectual property rights. We are committed to protecting the specific R&D outcomes of pharmaceutical development companies, continuously expanding the protection and influence of the product lifecycle of new drugs, and leveraging this to enter global markets.

2. Patent Rights for Medicinal Access Superior to New Drugs

We adjust our operational strategies based on the needs of patients in different regions and the accessibility of medicines; considering that least developed countries may not afford or access innovative medicines due to intellectual property rights protections, in addition to considering the prevalence of the condition, local economic levels, and local government policies on new drugs, we also take into account the actual situations in low-income countries and least developed countries (LIC/LDC) from an intellectual property management perspective to meet local patients' needs for drug access. For instance, when choosing between exercising patent rights and humanitarian aid, priority is given to medical needs, providing channels for drug accessibility and affordable prices, allowing patients access to patented new drugs. In 2023, PharmaEssentia did not apply for or enforce patents in any low-income or least developed countries.

92
Valid Patents

118
Valid Trademarks

Intellectual Property Education and Training

In 2023, PharmaEssentia conducted four sessions of intellectual property-related training for R&D directors and R&D personnel in the United States (PIRC) and Taipei headquarters, totaling 53 hours.

Patent and Trademark Management

PharmaEssentia places great emphasis on patent protection and management, in line with the intellectual property strategy of the group. We continuously pursue new patent and trademark applications. As of the end of 2023, PharmaEssentia has obtained 92 patents and 118 trademarks, with an additional 19 patents and 18 trademarks currently under application.

	Number of Patent	Number of Trademark
Obtained	92	118
Application Pending	19	18

Patent infringement, protection and specific measures

PharmaEssentia has taken a number of measures to ensure the protection of intellectual property rights against patent infringement. In terms of internal control system, the Company has formulated the "Regulations for the Management and Use of Intellectual Property Rights", which not only applies for patents in a timely manner to strengthen the protection of rights and interests in view of the risks of core patent rights, but also issues legal warnings or requests for compulsory orders from the court against suspected infringers. In terms of employee confidentiality obligations, the company and employees have signed employment contracts and confidentiality agreements, which clearly regulate confidentiality obligations and liability for breach of contract. Specific measures have also been taken to ensure non-infringement, including technology search and analysis at the start of R&D projects, ensuring that future development directions do not infringe on the technology of others, and monitoring the emergence of new technologies at any time during the development process.

Through these comprehensive measures and systems, PharmaEssentia is able to effectively protect the key core technologies developed by itself and avoid significant impact on the company due to negligence in R&D or technology-related links.

2.7 Ethical Marketing of Pharmaceuticals

Materiality Assessment

GRI 417-3 | HC-BP-270a.2, 510a.2

PharmaEssentia's ethical marketing policy governs the interactions between pharmaceutical professionals and medical institutions, as well as healthcare professionals, ensuring the welfare of patients is maintained.

Materiality Assessment

Ethical Marketing Policy

Impact Assessment

Global standards require ethical behavior in drug marketing, prioritizing patient welfare, including compliance with WHO, IRPMA, PhRMA, and NCP-DP standards.

Responsible Entities

Marketing departments and medical affairs teams at Taiwan headquarters and subsidiaries, coordinated by the Sustainability Development Center: Access to Health care Team and Product Safety and Ethics Team.

Management Policies and Commitments

This policy mainly regulates the behavior of PharmaEssentia personnel in drug marketing; advocates this policy for all internal employees who interact with medical service professionals every year, and annually conducts process reviews for all activities, marketing documents, and daily operations. Based on seven principles:

1. Patient health and welfare priority.
2. High standards for quality, safety, and efficacy.
3. Ethical interactions: ethically, appropriately and professionally when interacting with relevant entities or individuals. Do not provide or supply any goods and services that may directly or indirectly cause undue influence
4. Accurate information: providing correct, balanced and scientifically valid product information
5. Ethical marketing: marketing activities are ethical, correct and balanced. There must be no risk of misleading. Product marketing information must include a proper assessment of the risks and benefits of the product and how to use it appropriately
6. Privacy respect: respect patients' privacy and personal information
7. Transparent research: sponsored/supported clinical trials or scientific research for the purpose of pursuing new knowledge, enhancing the interests of patients and promoting the progress of medical science and technology; maintain transparency in industry-sponsored human clinical trials.

Indicators and Goals

Zero violations.

Effective Implementation Measures

Regular internal reviews by relevant teams to ensure effective implementation.

- **2023 Performance**

No violations in ethical pharmaceutical marketing across all countries.