

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	-lus	Business Integrity Code	Code of Ethical Conduct
CT -Au	Business Integrity Operating Procedures and Behavior Guidelines	A Star	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			
	New drug development and preclinical research	<ul> <li>✓ Good laboratory practice (GLP)</li> <li>✓ Non-clinical safety standards for drug testing established by regulatory agencies in each country</li> </ul>				
Before market launch	Clinical trials	<ul> <li>Good clinical practice (GCP)</li> <li>Good manufacturing practice (GMP)</li> <li>Ethical principles of the Helsinki Declaration</li> <li>Local regulations established by regulatory agencies, such as Taiwan's "Regulations for Human Clinical Trials" and "Pharmaceutical Affairs Act"</li> </ul>	<ul> <li>Establishing a legal compliance committee</li> <li>Setting up an anonymous hotline for reporting violations</li> <li>Establishing a dedicated section for legal compliance-related measures</li> <li>Ensuring all functional departments adhere to legal compliance-related measures</li> <li>100% coverage of employee training on legal compliance</li> <li>Monitoring system for meals provided to healthcare professionals</li> <li>Business rules and operations for speaking events</li> <li>Ethical guidelines for pre-clinical animal testing</li> <li>Ethical guidelines for clinical human trials</li> </ul>			
	Production and mann- ufacturing	<ul> <li>Good distribution parctice (GDP)</li> <li>Good manufacturing practice (GMP)</li> <li>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 Pharma- ceutical Manufacturing Plants"</li> </ul>				
	Drug registration	✓ Local regulations established by regulatory agencies, such as Taiwan's "Guide- lines for Inspection, Registartion, and Review of Pharmaceutical Products"				
After market launch	Marketing and sales	<ul> <li>Good distribution practice (GDP)</li> <li>Relevant ethical regulations established by the World Health Organization (WHO) and regulatory agencies in various countries</li> </ul>	<ul> <li>Implementing a transparent reporting system</li> <li>Implementing a review proess and control measures for speaking events, advisory committees, and the monitoring and auditing system for meals provided to healthcare professionals</li> <li>Implementing a compliance review process and control measures for advisory committees</li> <li>Other legal compliance policies and standard operating procedures, such as investigations, monitoring, and employee discipline</li> <li>Pharmaceutical marketing ethics guidelines</li> </ul>			
	Pharmacovigilance	<ul> <li>Good pharmacovigilance practice (GVP)</li> <li>Local regulations established by regulatory agencies, such as Taiwan's Pharmacovigilance Management Measures</li> </ul>				

## 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.

Ξ