Materiality Matrix in the Year of Sustainability Performance GRI 102-47

Material, moderate, and general sustainability topics are determined by cross-referencing the "level of impact on the sustainability topics" and "level of stakeholders' concern" on the material sustainability matrix. This report comprehensively discloses the management approaches and performance information of the 11 material topics and continues to monitor and manage the rest of the topics.



6 Risk Management

Risk Management Organization and Mechanism GRI 102-11 GRI 102-15

PharmaEssentia properly manages all risks that correspond with material topics and has formulated risk management policies, procedures, and internal control systems based on relevant standards and rules. For financial risks such as market risk, credit risk, and liquidity risk, all relevant financial activities are carried out in line with PEC's internal control mechanisms. And all major financial activities shall be reviewed by the Board of Directors in line with relevant standards and the internal control system. The Auditing Office also reviews such activities and reports them to the Board. The Execution Center for Corporate Sustainability oversees coordinating non-financial risk identifications relate to ESG aspects. It oversees the likelihood and level of impact of risks for business operations, and provide feedback on existing management mechanisms to the management approaches to material topics. To effectively prevent risks and hazards, PharmaEssentia has further formulated management practices against emerging risks to identify the types of risks that are new or are expected to have potential/longterm effects on the Company's operations and business activities. Their impacts on PharmaEssentia's operations are analyzed: relevant management mechanisms are actively formulated; and the management effectiveness is regularly monitored.



Note: Please refer to "2.1 ParmaEssentia's Governance Framework" for PEC' risk management organization.

Identifying Non-financial Risks

In line with the 2018 Corporate Risk Management Framework from the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and the World Business Council for Sustainable Development (WBCSD), PharmaEssentia's non-financial risks of PharmaEssentia are identified through understanding the likelihood and impact of risks through organized and structured COSO framework, which management mechanisms and future action plans are planned accordingly. Our process of identifying non-financial risks is described below.

Environmental

Impacts



Understanding the importance of risk to **PharmaEssentia**

 Global and industrial ESG risk trends Case sharing

Listing potential risks in terms of likelihood of occurrence and impact

- Impact level: Strategic, operational, financial, and compliance aspects
- Likelihood: Whether the risk has occurred in the past and chances of it happening going forward



Risk issues in the order of importance

· Complete the risk matrix in two dimensions: likelihood of occurrence and impact



Planning of risk response strategy

 The main investment and action plan will be developed according to the ranking of risks in the future

Existing Management Mechanism and Future Optimization Actions for Non-financial Risk Issues

For the risks that have been identified, we are making actual improvements based on the existing management mechanisms and reviewing, optimizing the improvement plans going forward in order to further feedback to the management approaches to the material topics. Since PharmaEssentia has re-identified the material topics in 2021, certain existing material topics have been deemed as either moderate or general topics. Nevertheless, we will continue to follow up on the risks associated with such topics and to actively manage them accordingly. (Risks denoted with [©] indicate emerging risks, while the ones denoted with ★ refer to material sustainability issues for 2021. Please refer to "Preamble 5 Identifying Material Topics")





| | Environmental | | Governance |
|---|---|---|---|
| Risk Issues | Improper storage and management of chemicals | Improper storage and management of waste | Product safety monitoring mechanism failure |
| Material Topics | Hazardous Substance Management * | Waste Management * | Drug Quality & Safety Management |
| Possibilities/ Existing Management Mechanisms | Adhere to the restricted operating volume and reporting schedule from the competent authority. Handle disposal of chemicals and waste in accordance with the internal chemical and Waste Management procedures. Join the regional toxic chemical substance disaster prevention organization | Adhere to the restricted operating volume and reporting schedule from the competent authority. Handle disposals in accordance with internal waste management procedures. | Regularly confirm the numbers and items of safety incidents reported by CROs. Regularly confirm the contents and numbers of safety incidents/reports with subsidairies. |
| Likelihood of Occurence | | $\bullet \bullet \bullet \bullet \bullet$ | |
| Severity | $\bullet \bullet \bullet \bullet \bullet$ | $\bullet \bullet \bullet \bullet \bullet$ | |
| Actual Improvement Actions in 2021 | Continue to practice transportation standards of toxic chemical substances and to follow the routine reporting system to reduce the risk of toxic chemical hazards. Taichung Plant commissions legitimate vendors to dispose of waste toxic chemical substances and the competent authority is also notified for review. Taichung Plant was permitted to join Taichung City's toxic and concerned chemical substance regional joint prevention organization. No deficiency was found during Taichung Plant's audit. | Outsource waste disposal and clearance in line with regulations from the competent authority. Inspected temporary waste storage area at Taichung Plant in line with applicable laws and regulations (4 times/ year) and conducted annual audit on waste disposal vendor (twice/year); no abnormality was found. Taichung Plant submitted application for change in "Commercial/industrial waste disposal plan" based on the characteristics of the waste, source of waste generation, and volume of the wate generated etc. No deficiency was found during Taichung Plant's audit. | Determine the competency of the drug safety CROs by evaluating the quality and completion time of the Periodic Safety Update Report (PSUR) and Periodic Benefit-Risk Evaluation Report. Ask CROs to regularly confirm the numbers of safety incident reported every month. |
| Expected Improvement Actions for 2022 and Onward | Taichung Plant to implement ISO45001 Occupational Safety and Health Management Systems \ ISO14001: 2015 Environmental Management Systems in 2023 Disclose the annual greenhouse gas emissions, water consumption, and total volume of waste generation over the years. Monitor anticipated environmental protection laws and information on revision/amendment announcements to follow legal regulations and control. Revise plant implementations and management measures as soon as possible. Strengthen employees' emergency response skills by requiring operators of toxic chemical substances to participate in external professional personnel training courses regarding response measures to toxic and concerned chemical substances. | | Determine the competency of the drug safety CROs outsourced by subsidiaries through evaluating the quality and completion time of their reports. Continue to develop and amend standard operating procedures (SOP) related to drug safety. Increase the manpower in Pharmacovigilance department at PharmaEssentia's headquarters to ensure pharmacovigilance and legal compliance of drug safety monitoring tasks. |
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Appendix

| | Governance | | |
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| Risk Issues | Severe plant inspection deficiencies | Product endangering patient life safety | Improper management of product transportation |
| Material Topics | Drug Quality & Safety Management * | Drug Quality & Safety Management * Patient Relation and Community Engagement * | Drug Quality & Safety Management * Supply Chain Management * |
| Possibilities/ Existing Management Mechanisms | Each internal department shall undergo internal quality audit every year. Foreign experts are invited to conduct quality audits when necessary. | Ensure complete collection of safety information through various adverse drug event reporting channels, which are disclosed on the Company's official website. Accurately report serious adverse events. | Strictly control the packaging and transportation process to ensure the products are stored within 2°C to 8°C, and to regularly maintain the refrigeration equipment required. Comply with the Good Distribution Process (GDP) for drugs and medications. |
| Likelihood of Occurence | | | |
| Severity | • • • • • | • • • • • | • • • • • |
| Actual Improvement Actions in 2021 | Deployed digitized document management, training, and quality management systems Engaged in weekly online discus- sions with consultant in preparation for the U.S. FDA plant inspection. Invited American consultants to conduct onsite quality audit and continued to optimize our quality system. The U.S. FDA completed the GMP plant inspection at PEC's Tai- chung Plant in September, and we successfully obtained regulatory marketing approval in November. | Toll-free Medical Information Consulting Call Center hotline set up by professional management/consulting company is used to announce/report relevant business activities with medical institu- tions and pharmacovigilance QA personnel from the plants. The electronic mailbox used for receiving drug safety reports has been announced on the website of PEC's Taiwan headquarters. The electronic mailbox that represents PharmaEssentia at the drug safety CROs is used to receive safety/adverse events from all coun- tries where PEC products have been launched. Staff from clinical trials and business divisions all pay active at- tention to adverse events related to PEC's products. Any serious adverse event is reported to the competent authority within 15 days as required by the law. Drug safety monitoring training is given to all new employees at PharmaEssentia. | Utilized mean kinetic temperature (MKT) to evaluate temperature deviation risks in line with the United States Pharmacopeia (USP). Completed audit procedures for 4 contracted transportation companies. Built and deployed large-scale cold chain space, where the output of cold chain products is carried out; all output has met product temperature control requirements throughout the transportation process since the third quarter (Q3) Verified by the TFDA and the U.S. FDA through plant inspection that all output operations and completeness of documentation process have met cGMP/GDP requirements. |
| Expected Improvement Actions for 2022 and Onward | Deployed more digitized quality management procedures. Continued to review quality and invited the EU consultants and experts to review and optimize existing systems in preparation for the EU plant inspection | We actively engage in signal testing based on the safety signal management standards from GVP Module IX, in which we actively search for and identify safety signals from various sources, including individual case safety report (ICSR) and scientific papers and reviews. Safety evaluation on Signal Detection Report is conducted every three months. Collaborate with QA department in Taichung Plant to handle product complaints related to adverse response. Signed Safety Data Exchange Agreements (SDEA) with strategic partners abroad to exchange information related to drug safety from various countries to meet relevant legal requirements. | While transporting output to the logistics center, our U.S. OEM used coolers to control the temperature on top of air freight and truck, and we are proposing to also deploy refrigerated trucks as a means of transportation. Continue to execute external audit plan. Besides maintaining existing compliance procedures, we will also continue to update relevant transportation and sales records in line with international laws and regulations to build a comprehensive drug traceability management system. |

| | Governance | |
|---|---|---|
| Risk Issues | R&D and business development directions are not closely aligned | Improper management of outsourced suppliers |
| Material Topics | R&D and Innovation of New Drugs* | Supply Chain Management * |
| Possibilities/ Existing Management Mechanisms | R&D internal control rules and regulations and related management methods. Due diligence mechanism and relevant training | Establish supplier evaluation mechanism. Perform various validation and verification. External audit program. Sign supply or quality contracts. Provide outsourced CMOs with demand forecast and to update the forecast in a timely manner. Establish channels of communication with outsourced vendors to achieve real-time review over relevant quality events and to determine subsequent actions. Outsourced activities policy Product packaging and labeling policy |
| Likelihood of Occurence | $\bullet \bullet \circ \bullet$ | |
| Severity | $\bullet \bullet \circ \bullet \bullet$ | • • • • • |
| Actual Improvement Actions in 2021 | At the beginning of each new project, in-depth data collection should be conducted to understand the clinical progress of competitive drugs, PEC should conduct in-depth evaluation to tap into unmet drug needs and commercialization opportunities in the market and to guide the drug development progress through the development platform. Engage in market analysis of existing drug development projects and coordinate with Marketing Department to understand market opportunities; dynamically report on the market's potential risk to the management team and to adopt rolling review over current R&D projects. | Achieve bi-lateral communications with suppliers and maintain partnership to achieve timely support from suppliers in responding to production and market demand Deployed 3 secondary sources of material while the supply chain was rendered unstable by the pandemic; supplies of all other materials continued to be normal |
| Expected Improvement Actions for 2022 and Onward | R&D department will actively evaluate the feasibility of launching the new project using drug market database and to encourage other staff to engage in training related to market analysis. Provide rolling adjustment and feedback on market trends to each project, and to regularly report to the management team during the bi-weekly R&D meeting to increase the project team and management team's market awareness and risk evaluation skills regarding R&D projects. Formulate a R&D and marketing collaborative platform and procedures to promote inter-departmental facilitation and to increase the R&D team's market analysis skills. | Continued to formulate Code of Conduct for Suppliers Continued to develop and deploy secondary sources of material to reduce the risk of supply chain disruptions |
| | <i>©</i> * # \$ | * * * |

| | Governance | | |
|---|---|---|--|
| Risk Issues | Unable to provide stable or timely supply of products | Violations of the code of business conduct and legal compliance | |
| Material Topics | Supply Chain Management *, Access to Medicine * | Business Ethics & Compliance *, Access to Medicine * | |
| Possibilities/ Existing Management Mechanisms | Pre-plan and confirm production scheduling. Establish safe inventory and secondary source of material. Coordinate and arrange the transportation operation based on the drug's required temperature setting. QA devision will confirm the relevant documents and operations meet the standards for product release. Quarterly commercial and clinical development demand forecast. Risk management policy Raw material management policy Drug safety reporting system and supply shortage notification system from the competent authorities in each country PEC's drug complaint system | PEC has formulated and enacted the "<u>Corporate Governance Code</u>" the "<u>Principles of Ethical Corporate Management</u>," the "<u>Codes of Ethical Conduct</u>," the "<u>Procedures for Ethical Management and Guidelines for Conduct</u>," the "<u>Corporate Social Responsibility Best Practice Principles</u>" and the "<u>Operating Procedures for Handling Material Nonpublic Information and Preventing Insider Trading</u>." The Group has established internal control and internal audit management system and more than 40 operational management rules at the headquarters. The U.S. Subsidiary has also formulated more than 20 legal compliance policies. From research and development to product commercialization, all business ethics and integrity of business conduct are required to comply with external regulations. | |
| Likelihood of Occurence | | | |
| Severity | $\bullet \bullet \bullet \bullet \bullet$ | $\bullet \bullet \bullet \circ \bullet$ | |
| Actual Improvement Actions in 2021 | Maintain sufficient inventory and achieve timely supply of all drugs based on their respective demand by utilizing the production planning and raw material planning system and tools. Build a large-scale cold chain space to increase the flexibility in storage and turnover of cold chain products. Technological transfer is gradually completed for the new product's production line (PEG). Expanded plant operations and office space in the fourth quater (Q4). Improved the operational technology of biopharmaceutical manufacturing process and successfully passed the inspections from the U.S. FDA. Actively maintain mutually trusting and beneficial relations with suppliers through increasing the frequency of communications to maintain stable raw material supplies, and to stay up to date on inventories of external suppliers in Taiwan, global supply, and demand status, and achieve inter-departmental collaborations on inventory preparations. Deployed 3 secondary sources of material while the supply chain was rendered unstable | Promoted "Top Management Principles for Group Business Conduct and Ethics" and related detailed operational policies formulated by Headquarters. Actively implemented the FSC's Corporate Governance 3.0 Blueprint of Sustain- able Development Evaluation Index. | |
| Expected Improvement Actions for 2022 and Onward | by the pandemic; supplies of all other materials continued to be normal Deployed more comprehensive corporate resource planning (ERP) system in January 2022. Maintained functionalities of existing facilities and equipment. Continued to maintain good interaction with suppliers. Continued to develop and deploy secondary sources of material to reduce the risk of supply chain disruptions. | Establish an inter-compliance committee within the Group and coordinate organizational procedures. Facilitate strategic decision-making processes by incorporating input from functional compliance representatives to achieve compliance with applicable laws and PEC's policies throughout all operational activities. Ensure that operations comply with legal requirements both at home and abroad | |

| | Governance | | |
|---|---|---|---|
| Risk Issues | Inadequate quality assurance of clin- ical operating procedures | Attacks on network safety and private or confidential data $^{\circ}$ | Inadequate protection and control of intellectual prop- erty and defense against infringement of rights [©] |
| Material Topics | Drug Quality & Safety Management *, Access to Medicine * | Information Security and Cybersecurity, <u>Human Rights</u> * | Intellectual Property, <u>Business Ethics & Compliance</u> * |
| Possibilities/ Existing Management Mechanisms | Implement management methods based on the existing QA department and QA system. | Firewall, antivirus softwares Update, strengthen software and hardware equipment | Intellectual Property Rights Management and Utilization Regulations. PEC's Legal Department and attorneys Corporate Governance Best Practice Principles Internal Control and Audit System and Management |
| Likelihood of Occurence | | $\bullet \bullet \bullet \bullet \bullet$ | $\bullet \bullet \bullet \bullet \bullet$ |
| Severity | • • • • • | • • • • • | $\bullet \bullet \bullet \bullet \bullet$ |
| Actual Improvement Actions in 2021 | Actively recruited clinical quality assurance (CQA) staff on talent recruitment websites. Clinical Operations department has com- pleted 20 SOPs related to clinical oper- ations, including audit management and quality management system and more. Clinical Operations personnel will temporarily assume drug safety monitoring QA functions | Upgraded the firewall hardware from PA220 to PA820 Completed the draft for information safety policy and procedures Planned relevant information security protection measures to be enforced in 2022 | Since our patented new drug BESREMI[®] has obtained regulatory marketing approval at various countries, in addition to undertaking the basic IP protection around the world using our existing patent, we have also asked external pharmaceutical IP experts to facilitate the planning and filing for new patents. |
| Expected Improvement Actions for 2022 and Onward | Completed recruitment of CQA staff. Formulated annual QA plan for drug safety monitoring and implemented QA activities. Amended clinical operations SOP related to quality assurance and drug safety monitoring SOP based on future legal updates and or- ganizational adjustments. | Completed the following measures in February 2022 Information security advocacy and social engineering training Replaced weaker thumb drive-based control with DLP total solution Completed vulnerability scanning and improved major vulnerabilities Phase 1 of data storage equipment management over major mainframes Completed the draft for information safety policy and procedures and submitted the draft to the Board of Directors Planned and executed the "data encryption system", "data loss prevention (DLP) system", and "cloud-based multi-factor authentication (MFA) mechanism" to strengthen information security and authentication security advocacy and social engineering training to be completed in October 2022 | Innovative reward system. Forfeit the opportunity to enter certain markets if necessary. Introduction and implementation of FTO (Free to Operate). Deploy infringement detection mechanisms in our marketing system Deploy due diligence mechanism and training for technologies that PEC is interested in acquiring Increase the enforceability of contracts Educational training. Establish audit mechanism to allow for timely inspection Data storage equipment management. |
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Appendix

| | Governance | |
|---|--|--|
| Risk Issues | Information disclosure is not in a time, transparent, or effective manner [®] | International arbitration and litigation disputes |
| Material Topics | Corporate Governance | Corporate Governance |
| Possibilities/ Existing Management Mechanisms | Procedures for Handling Material Inside Information and Prevention of Insider Trading Material information as defined by the verification and public handling procedures of material information from TWSE or TPEx listed companies from the competent authority. | Audit Committee FSC corporate governance evaluation system indicators. Board of Directors and director evaluation mechanism. Internal auditing operations. Comply with the relevant procedures enacted by the competent authorities. Procedures for Handling Material Inside Information and Prevention of Insider Trading For more information, please refer to the MOPS, PEC's website, <u>2021 Annual Report</u>, and financial statements |
| Likelihood of Occurence | $\bullet \bullet \bullet \bullet \bullet$ | $\bullet \bullet \bullet \circ \bullet$ |
| Severity | $\bullet \bullet \bullet \bullet \bullet$ | $\bullet \bullet \bullet \bullet \circ$ |
| Actual Improvement Actions in 2021 | PEC complies with the information disclosure requirement for TWSE/TPEx list- ed companies from the competent authority, has acquired financial reporting competencies, and discloses financial information in a timely manner. Amended PEC's Procedures for Handling Material Inside Information and Prevention of Insider Trading in line with the regulations from the competent authority and executes the Procedures in operations. Third-party verification by an independent institution is conducted for the sustainability report. | Optimized the internal control over procedures related to litigations monitoring the progress of PEC's major litigations to effectively manage and control over the contents of external legal documents Reinforced the information relay between PEC's material information team to engage in more effective horizontal communications The newly formulated "Management Procedures for Litigations and Material Disputes" from the Legal Department will strengthen the control over international arbitrations and litigations". Continue to practice diversified policy and arrange diverse continuing education courses for members of the Board of Directors to enhance their decision-making quality and strengthen the functions of the Board. |
| Expected Improvement Actions for 2022 and Onward | Continue to implement PEC's Procedures for Handling Material Inside Information and Prevention of Insider Trading and to advocate said Proce- dures to responsible personnel. Implement and comply with disclosure standards from relevant laws and regulations from competent authorities both at home and abroad. Adopted third-party verification mechanism for the sustainability report. | PEC has made the material announcement on February 15, 2022, that, upon the final ruling from the Federal Court of Justice in Germany over the international arbitrary with AOP, that PEC does not need to pay compensations and interests from the previous arbitrary ruling (Documents related to legal case number: I ZB 21/21) Legal Department plans to undertake the following control measures over litigations and non-litigious lawsuits: Optimize lawsuits and legal document management archive, formulate a lawsuit process monitoring system, and to set a process management model for similar cases in the future. |
| | | |

| | Governance | Environmental |
|---|--|--|
| Risk Issues | Functions of the Board that require improvements | Climate Risk [®] |
| Material Topics | Corporate Governance | Climate Governance * |
| Possibilities/ Existing Management Mechanisms | Audit Committee FSC corporate governance evaluation system indicators. Board of Directors and director evaluation mechanism. Internal auditing operations. Comply with the relevant procedures enacted by the competent authorities. | Contents of the Internal Greenhouse Gas Management Procedures Carry out internal training, data collection, internal audit, and external verifications. Corporate governance 3.0 evaluation system Task Force on Climate-related Financial Disclosures (TCFD) |
| Likelihood of Occurence | $\bullet \bullet \bullet \bullet \bullet \bullet$ | $\bullet \bullet \bullet \bullet \bullet$ |
| Severity | $\bullet \bullet \bullet \bullet \bullet$ | $\bullet \bullet \bullet \bullet \bullet$ |
| Actual Improvement Actions in 2021 | Actively implemented the FSC's Corporate Governance 3.0 Blueprint of Sustainable Development Evaluation Index. A Corporate Governance Officer has been set up; the role is served by Hsueh-Ling Chang, Deputy Divisional Head of Finance and Accounting Department from the Head Office, who will assist the Directors to perform their duties, provide needed information, and arrange continuing studies courses based on the Directors' needs. PEC identified the non-financial ESG-related risks based on the corporate risk management framework co-published by the COSO and WBCSD. Invited external evaluation agency to conduct external assessment over the Company's Board of Directors; please refer to disclosures on PEC's website for the assessment results. | As a forefront in climate governance, the GHG reductions team has been formulated at Taichung Plant, and "Greenhouse Gas Management Procedures" has been formulated Completed 2019 GHG inventories in October 2021 and received ISO 14064-1 third-party external assurance certification. Introduced TCFD educational training course for the first time; total number of participants from the ESG functional groups was 40, reaching a 76.92% attendance rate. Gained awareness to the climate risks and opportunities in PharmaEssentia's value chain through the course and such knowledge will serve as important information for internal decision-making. |
| Expected Improvement Actions for 2022 and Onward | PEC will formulate a nomination committee based on actual operational needs in order to continuously strengthen the nomination system of Directors. Arrange continuing studies to enhance the professional functions of the Board of Directors based on the needs and willingness of the Directors. Reinforced supervision of the Board of Directors over PEC's audit system practices, and regularly arranged for communications between the internal auditor and Independent Directors. Regularly conducted the performance evaluation of the Board of Directors and the functional committees. Submitted evaluation reports and substantive improvement proposals to the Board. In 2022, PEC expects to formulate a Sustainable Development Committee, which will be directly overseen by the Board of Directors. The Sustainable Development Committee will strengthen risk management and enhance contingency responsiveness, thereby achieving the goal of risk control. | Taichung Plant will carry out 2020 and 2021 GHG inventories in 2022, and it will also implement ISO45001 Occupational Safety and Health Management Systems and ISO14001: 2015 Environmental Management Systems in 2023 Information on climate governance is disclosed in the Annual Report and sustainability report in line with applicable laws and the Corporate Governance 3.0 Standards Integrated potential effects from climate change in PEC's strategic planning, analysis, and risk management in line with the TCFD framework |
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