6-1 Governance on Access to Medicine

SASB | HC-BP-240a.1

Materiality Topic

Corporate philosophy and strategy

Based on the 3 principles of Access to Medicine Index, including Accessibility, Affordability, and Availability.

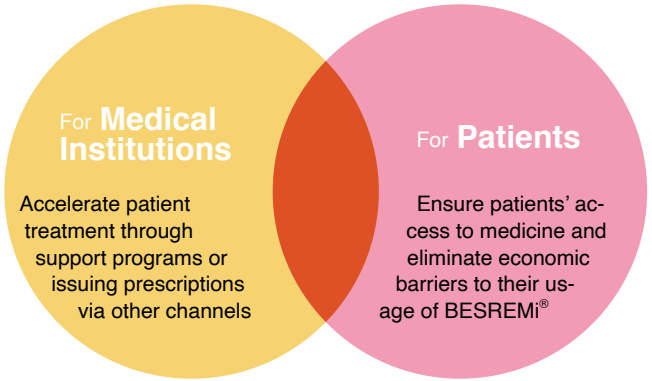
Core concept and commitment

Eliminate the pain of patients and promote the health and well-being of all mankind with our new pharmaceutical products

Strategic Objectives and Access to Medicine Plans

Close-use management of access to medicine closely integrated with business strategies

- Combined with business development strategies, the Board of Directors and senior-level management of subsidiaries in various regions to promote the access to medicine.
- Strictly following the relevant laws and ethical regulations involved in each stage of the product life cycle (please refer to Chapter 2).



Value Chain Stages	Access to Medicine Strategies		2021 Action Plans and Performance
R&D of new drugs	Early-stage R&D	Continue to develop innovative drugs	• Modifying existing drugs to reduce the risks of new drug development • Utilizing technology platform to effectively develop diverse products • 4 pre-clinical trials are being carried out successfully (please refer to Section 1.3 "R&D of Innovative Biopharmaceuticals" • Total R&D expense reached NT$1.27 billion; 83 R&D personnel (accounting for 23.3% of total employees) throughout the world are committed to satisfying the unmet medical needs
	IP Management	Active Industry-Academia Partnership and Research	• Engaged in multinational industry-academic partnership with Athenex and Axis Therapeutics • Commits to take into consideration the **access to medicine of patients in low income countries and least developed countries** when utilizing and applying for patents • Clinical trials and post-marketing sales of new drugs worldwide through licensing in and licensing out
Clinical Development	Clinical Trial	Clinical trials at medical institutions throughout the world	• Launching multi-country and multi-center clinical trials with procedures that comply with relevant laws, regulations, and ethical standards • Commits to assist patients who meet criteria to obtain legal access to proper treatment • Simultaneously promoted more than **20 clinical trials**; trial data can also be used as a basis for regulatory marketing approval approval and the drug application from physicians
	Compassionate Use	Support patients with critical conditions	• Provide compassionate use to patients with severe or life-threatening diseases who did not participate in clinical trials; such patients may apply to use experimental new drugs that have passed scientific research but have not yet been launched to begin urgent treatment. • In 2021, **number of patients around the world who benefited from compassionate use reached 40 patients**

Value Chain Stages	Access to Medicine Strategies		2021 Action Plans and Performance
Production and Manufacturing	Product Quality	Rigorous product manufacturing that meet regulatory compliance	• Manufacturing process has been approved and tested, and obtained GMP certifications from US FDA, EU EMA, and TFDA
	Logistics and Supply	Timely and Stable Medicine Supply	• Built safe and stable drug supply chain in Taiwan and worldwide
Regulatory Marketing Approval Application	Regulatory Marketing Approval Application	Actively obtained licenses from multiple countries	• Short- and mid-term drug license application plans around the world. • **Currently, BESREMi® has been granted regulatory marketing approval in 37 countries** and the number of regulatory marketing approvals continue to increase, thereby improving the rights to medical access to patients throughout the world.
Market Access	Reasonable Pricing	Proving the economic values of products	• Fair, reasonable and affordable drug pricing. • Analyze product value using **Pharmacoeconomics and Health Technology Assessment (HTA)**, evaluate benefits and risks of the products in medical and economic systems of various countries and realize **appropriateness and sustainability of pricing strategy in the U.S. & Europe**
	Patient Support	Provide resources to accelerate treatment	• **PharmaEssentia SOURCE** (online portal) is the source for patient support and education in US market . – SOURCE offers personalized support services designed to help US patients or caregivers successfully start and stay on BESREMi®. – SOURCE supports the U.S. Healthcare professional your Patients' Access to BESREMi®, can guide your patients through the access and reimbursement process and offer personalized support through their treatment . • Established the **first MPN center** in Taiwan

Value Chain Stages	Access to Medicine Strategies		2021 Action Plans and Performance
Marketing and Sales	Academic Exchange	Demonstrating the medical value of products through academic exchange	• Sponsoring **the conference on Myeloproliferative Neoplasms Asia (MPN Asia)**. • Cooperate with value chain partners to strengthen social influence on the local biotechnology and pharmaceutical industry. • Promote initiatives and support organizational activities on issues related to access to medicine
	Medical Contribution	Reduce gap in medical access	• As of December 31, 2021, **more than 1,500 patients have used BESREMi® in treatment** • Accumulated hundreds of activities with PV Organization and supported patient organizations in the U.S.
Patient Safety	Immediate Reporting	Established an immediate reporting system	• PEC headquarters' **adverse reaction reporting mailbox**: Safety@pharmaessentia.com • CRO set up **global adverse reaction reporting mailbox**: PharmaEssentia.drug-safety@labcorp.com • A **dedicated reporting management center PEC U.S. Call Center (800) 999-2449** that caters to the U.S. Market and is in charge of handling drug quality and safety demand and reporting information was set up in November 2021
	Serialized Products	High-tech Serialized Products	• **Drug serialization** has been completed in 2020, in which injection preparations OEM Pyramid Laboratories Inc. will be responsible for the packaging and serialization of pharmaceutical products to comply with relevant regulations from the U.S.'s Drug Supply Chain Security (DSCSA)
	Product Recall	Product Recall Management Mechanism	• A comprehensive product traceability mechanism was set up, and **no adverse drug recalls have occurred** in 2021

Management Approach on Access to Medicine

GRI 103-2~3 GRI 203-1

Policies

Internal Policy

- Draft on Clinical Study Policy
- Draft on Compassionate Use Policy
- Standardized operating procedures related to clinical trials
- Standardized operating procedures related to Compassionate Use Policy

External Guidelines

- International laws and standards
- ICH E6 Good Clinical Practice
- Local laws and standards (take Taiwan for example)
  - Pharmaceutical Affairs Act
  - Medical Care Act
  - Human Subjects Research Act
  - Personal Data Protection Act
  - Regulations on Human Trials
  - Good Clinical Practice, GCP
  - Regulations on Management of Medical Samples and Gifts

Commitments

PEC commits to adherence with relevant international and local laws and standards, and uses our strengths to implement the three approaches of access to medicine strategies from the Access to Medicine Index: Governance on Access to Medicine, Research & Development, and Product Delivery. We expect to contribute to the improvement of global health with our technology and expertise, and committed to following the 5 major aspects of access to medicine strategies:

1. Enhance the management strategies of drug accessibility.
2. Innovative medicine – addressing unmet medical needs
3. Responsible and transparent intellectual property right management
4. Provide stable and safe medicines.
5. Leading the industry development to enhance the local capabilities.

Responsibilities

- Currently, the Board of Directors and the senior management team of each subsidiary act as issue managers and implement governance on access to medicine in conjunction with the business strategies within the current system
- Execution Center for Corporate Sustainability - Access to Medicine Taskforce

Resources

- The Company's investment in promoting access to medicine is closely linked to all stages of our value chain, as described in the management approach to each material topic in each section. Most of these expenses are related to R&D expenses, which amounted to approximately NT$1.27 billion in 2021, while marketing expenses amounted to NT$956 million.

Goals & Targets

2022 Short-term Goals

- Obtain regulatory marketing approval for Ropeginterferon alfa-2b (P1101) for the treatment of PV in Macao.
- Obtain regulatory marketing approval for Tirbanibulin (KX01) for the treatment of actinic keratosis (AK) in Taiwan.
- Complete a reasonable and fair internal management policy for drug pricing to achieve global operational goals.
- Establish access to medicine policy.
- Implement health education programs to raise awareness of MPN disease and provide medical education to help patients understand the disease or obtain proper diagnosis and treatment, such as sponsoring the creation of the International Symposium on Myeloproliferative Neoplasms in Asia (MPN Asia) and sponsoring the American Society of Hematology (ASH).
- Strive to provide patients, families, physicians, caregivers, and other stakeholders in many different regulatory settings with appropriate information and opportunities to properly understand disease and the proper use of medicines.
- Establish a global logistics supply chain management system to provide stable, safe and high-quality pharmaceutical products through reliable manufacturing, and to effectively and responsibly manage the transportation and retrieval of pharmaceutical products to ensure that high quality products reach patients in a timely manner.
- Address unmet disease needs through innovative medicines such as value creation through innovation, access to medicine programs that integrate global R&D, initiation of multi-country, multi-center clinical trials, planning of short- to mid-term worldwide regulatory marketing approval programs, and transnational industry collaborations.

Goals & Targets

2023~2025 Mid-term Goals

- Obtain marketing approval for Ropeginterferon alfa-2b (P1101) for the treatment of PV in other Asian countries (to expand and develop the use of the drug in Southeast Asia), and Central and South American countries.
- Obtain marketing approval for ET in each participating country after completion of Phase 3 clinical trials of Ropeginterferon alfa-2b (P1101) in the U.S., Taiwan, China, Japan and South Korea.
- Establish the medicine life cycle management plan.
- Leading the industry development
- Cooperate with value chain partners to strengthen social influence on the local biotechnology and pharmaceutical industry.
- Promote initiatives on issues related to access to medicine.

2026 Long-term Goals

1. The goal is to accelerate regulatory marketing approval in all countries by 2026 and to integrate the Company's ability to support patients in developing or low- and middle-income countries with additional drug indications.
   - Promote Ropeginterferon alfa-2b (P1101) to enter Eastern Europe, Central Asia, and some African markets, and apply for regulatory marketing approval for PV to provide early access to patients in need.
   - Enter Southeast Asia, Central and South America, Eastern Europe, Central Asia, and some African markets to apply for regulatory marketing approval to market ET.
2. Responsible and transparent intellectual property right management
   - PEC commits to take into consideration the access to medicine of patients in low-income countries and least developed countries when utilizing and applying for patents to ensure the treatment needs of patients.
   - Conduct clinical trials and post-marketing sales of new drugs worldwide through licensing-in and licensing-out.

Evaluation of Management Approach

Mechanism of Evaluation

- Strictly follow the laws and external regulations involved in all phases of the product cycle from R&D to sales.
- Establish internal policies for ethical and responsible pharmaceutical supply, fair pricing, and international marketing compliance.
- PEC's Board of Directors and the senior management team of each subsidiary act as issue managers, and governance on access to medicine is consistent with business strategies within the current system.

2021 Evaluation Results

- BESREMi® has been granted regulatory marketing approval in 37 countries and the number of regulatory marketing approvals are still increasing, thereby improving the rights to medical access to patients throughout the world.
- BESREMi® was granted regulatory marketing approval as a first-line treatment for PV patients by the U.S. FDA in November 2021.
- Completed the formulation of the global supply chain for commercial use.
- Compassionate use has cumulatively benefited 40 patients worldwide, including 39 MPN patients in Taiwan, and 1 rare EDC disease in South Korea.
- Approved the implementation of a project for the importation of MPN-related diseases in Hong Kong.