



## 4.1 Governance on Access to Medicine

Material Topic

PharmaEssentia is committed to continuous research and development of new drugs, and through the Access to Medicine program, we strive to promote access to medication for patients around the world. Our core philosophy, to which we are committed, is to enhance drug accessibility, ensure affordability, and promote availability. We have formulated our group strategy guidelines based on the 2022 Access to Medicine Index framework to address unmet medical needs. Our goal is to reduce the gap in drug accessibility for pa-

tients, so that they can obtain the drugs they need in a reasonable, affordable, correct, and convenient manner. Through a drug accessibility governance policy that is closely integrated with our business development strategy, we aim to create shared value for patients. We also hope to use the power of the PharmaEssentia group to achieve **SDG 3- Good Health and Well-being** by 2030.

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Management Policy

### Internal Policies

- Clinical Study Policy (Draft)
- Compassionate Use Policy (Draft)
- Standard Operating Procedures related to Clinical Trials
- Standard Operating Procedures for Compassionate Use
- Intellectual Property Management and Utilization Measures

### External Guidelines

- International regulatory guidelines
- ICH E6 Good Clinical Practice
- Local country regulatory guidelines (e.g. Taiwan)
  - Pharmaceutical Affairs Act
  - Medical Care Act
  - Human Subjects Research Act
  - Personal Data Protection Act
  - Regulations Governing Human Research Ethics Review
  - Good Clinical Practice for Drugs
  - Regulations Governing Sample and Gift Offerings of Drugs



Management Commitment

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 6 major aspects of access to medicine strategies:

- Enhance the management strategies of drug accessibility.
- Innovative medicine – addressing unmet medical needs
- Responsible and transparent intellectual property right management
- Provide stable and safe medicines.
- Leading the industry development to enhance the local capabilities.
- Committed to developing innovative drugs to treat rare and ultra rare diseases, benefiting vulnerable patients



Accountable Units

- At present, the Board of Directors and senior management functional taskforces of each subsidiary are responsible for issue management, and the implementation of access to medicine governance is integrated with our business strategy within the current system.
- ECCS - Access to Medicine team



Input Resource

- The resources allocated for access to medicine is concentrated on research and development expenses and marketing expenses. Global R&D expenses are expected to reach around **NTD 1.43 billion, an increase of 12.5%** compared to last year, and marketing expenses are expected to reach around **NTD 1.54 billion, an increase of 63%** compared to last year.
- To enhance product life cycle management, the company has hired an international biopharmaceutical intellectual property lawyer by the end of 2022.
- A quarterly demand-forecasting mechanism for commercial and clinical development will be managed using the SAP S4 system starting from 2023.
- Manage **drug safety and supply shortage reporting systems** with regulatory authorities in different countries.
- Maintain and operate **the drug complaint system** established by PharmaEssentia Headquarters.
- Panco Healthcare meets the medication needs of patients in hospitals, and manages the medication pickup process in various hospitals.



**Targets**

**Short-term Targets for 2023**

- Ropeg is used to treat polycythemia vera (PV), a condition in which the body produces too many red blood cells
  - Obtaining approval for the drug in Japan
  - Submit drug license applications for Ropeg in Malaysia, Singapore, and Hong Kong
- Apply for coverage of Tirbanibulin (KX01) kinase inhibitor for the treatment of actinic keratosis under Taiwan's National Health Insurance program
- Establish internal pricing policies that are reasonable and fair in order to achieve global operational goals
- Strengthen the management system of global logistics supply chains, effectively manage drug transportation and recycling, and ensure that high-quality products are delivered to patients at the right time
- Initiation and application of research protocol
  - Initiate human clinical trials related to TCRT cell therapy
  - Complete IND application for Ropeg in treating epithelioid hemangioendothelioma, a very rare disease, in Taiwan
- Improve the technology for scaling up production for biologic drug processes and pass PMDA inspections in Japan
- Collaborate with Taiwan's National Health Insurance system to obtain hospital contracts and expand the use of medications beyond Panco Healthcare
- Continue to protect the patented new drug BESREMI<sup>®</sup> with the most basic global patent protections, be involved in the R&D process of PharmaEssentia, and continue to file new patent applications
- Establish an international-level research institution to expand the breadth and depth of new drugs that can be developed, and apply for intellectual property patents in a timely manner

**Medium-term Targets for 2024-2026**

- Ropeg
  - Obtain regulatory approval for the treatment of polycythemia vera (PV) in Southeast Asian and Central/South American countries
  - Obtain regulatory approval for the treatment of essential thrombocythemia (ET) after completing Phase 3 clinical trials in the United States, Taiwan, China, Japan, and South Korea
- Continue to strengthen drug life cycle management by continuously planning and applying for patents related to the substance and methods of the new drug, expanding exploration of new drug usage, collaborating with academic and research institutions in various countries, and enhancing social impact on the local biotech and biopharmaceutical industry with value chain partners
- Promote advocacy for issues related to access to medicine and collaborate fully with Panco Healthcare and subsidiaries to support the Group's new drug market launch process

**Long-term Targets (2026 and beyond)**

- Accelerate the application for drug approvals in each country, and integrate the prevalence of indications for the company's new drugs in developing countries for people with low to middle income into drug pricing strategies based on reasonable and fair pricing principles, while considering patients' ability to pay for the drug
- Ropeg
  - Obtain marketing authorization for the treatment of polycythemia vera (PV) in Eastern Europe, Central Asia, and Africa
  - Obtain marketing authorization for the treatment of essential thrombocythemia (ET) in Southeast Asia, Central and South America, Eastern Europe, Central Asia, and Africa
- Responsible and transparent intellectual property management
- When conducting patent layout, the company will gradually promote the use of drugs in low-income countries and developing countries based on the expansion of access to medicine in major industrialized countries, to ensure that the treatment needs of patients worldwide are met through licensing and external authorization as well as clinical trials and sales after launch conducted around the world



**Evaluation of Management Policy**

**Management Evaluation Mechanism**

- Rigorously comply with the laws and relevant regulations involved in the product cycle from research and development, production to sales
- Conduct drug supply, pricing, and international marketing in an ethical and responsible manner in accordance with internal policy

**2022 Evaluation Results**

- BESREMI<sup>®</sup> has obtained licenses in 38 countries and is expected to obtain a license in Japan in the first quarter of 2023.
- The board of directors has approved the drafting of a distribution and licensing agreement for Ropeg in Latin American with an international pharmaceutical company.
- Ropeg has been included in the reimbursement program of the largest hospital chain in the United States, the Kaiser Permanente.
- The Macau Health Bureau has granted approval for the import of Ropeg as a "pre-approved imported drug".
- The American NCCN treatment guidelines have listed BESREMI<sup>®</sup> as a treatment option for adult patients with polycythemia vera (PV).
- The Compassionate Use Program has benefited a total of 40 patients worldwide.
- A special import program for myeloproliferative neoplasms (MPNs) was executed in Hong Kong and Singapore.



**3,800+**

Over 3,800 patients worldwide have used BESREMI®



**40**

Patients who benefit from compassionate use



## Key Strategies and Actions on Access to Medicine

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To meet the medical needs of patients with rare diseases around the world, not only does PharmaEssentia address key issues at each stage of the value chain, but we also follow the [2022 Access to Medicine Index](#) framework to develop our strategies and policies as well as take concrete actions to promote the positive impact of drug repurposing.

### Corporate Purpose and Strategy

To solve the pain of patients and promote the health and well-being of all mankind with our new drug products.

### Core Vision and Commitments

- Improve Accessibility** | Provide drugs that can treat disease needs and supply them through legal and safe channels.
- Ensure Affordability** | Responsible, reasonable, and fair pricing mechanism.
- Enhance Availability** | Assist economically disadvantaged countries' patients in accessing the required drugs and reducing accessibility gaps.

### Strategy and Accessibility Plan

- Accessibility Governance** | **Access to medicine governance closely integrated with business strategies.**  
Promote access to medicine by the board of directors and senior management teams of subsidiaries.
- Meet the access to medicine needs of vulnerable groups.**  
Focus on the medical needs of economically or resource-poor patients, and provide assistance in resolving medical burdens.



**500+**

















Sponsoring underprivileged group patients to use BESREMI®









**For Patients**

Ensure access to medicine support for patients and eliminate economic barriers to using BESREMI®

**For Healthcare Institutions**

Accelerate patient treatment progress by providing support programs or other channels to prescribe BESREMI®

Value Chain	Issues	Strategy	Scope and Market	Impact	Correspond SDGs
 <p><b>New Drug Development</b></p>	<p><b>Early-stage research</b></p>	Continuously develop innovative drugs	<ul style="list-style-type: none"> <li>Create value through innovation and improvement of existing drugs to reduce the risk of developing new drugs</li> <li><b>Develop diverse products</b> effectively using technology platforms</li> </ul>	<ul style="list-style-type: none"> <li>Active investment in early R&amp;D with <b>NTD1.43 billion</b> spent and over 120 R&amp;D clinical staff globally</li> </ul>	 
	<p><b>Intellectual Property Management</b></p>	Actively collaborate with academia and industry for research			
 <p><b>Clinical Development</b></p>	<p><b>Clinical Trials</b></p>	Conduct global clinical trials	<p>Conduct multi-country and <b>multi-center clinical trials</b> following relevant laws, regulations, and ethical guidelines</p> <p><b>Provide timely medical assistance</b> to patients with serious or life-threatening diseases who cannot participate in clinical trials</p>	<ul style="list-style-type: none"> <li>Conducted over 20 clinical trials for the approval and prescription of new drugs, benefiting <b>over 850</b> clinical patients</li> <li>Continuously benefiting <b>40</b> people worldwide, improving medical access for vulnerable groups</li> </ul>	  
	<p><b>Compassionate Use</b></p>	Provide stable and timely supply of drugs			
 <p><b>Production and Manufacturing</b></p>	<p><b>Product Quality</b></p>	Produce and manufacture products in a strict and legal manner	<ul style="list-style-type: none"> <li>Production and <b>manufacturing processes</b> are approved and inspected according to international standards</li> <li><b>GMP certification</b> has been obtained from the FDA, EMA, TFDA, MFDS, and other regulatory bodies</li> </ul>	<ul style="list-style-type: none"> <li><b>Passed Japan's PMDA plant inspection</b> to ensure the safety of the production process and drug safety</li> <li>Regularly reviewing and evaluating the execution of injection filling, logistics, and supply chain</li> <li>In 2022, BESREMi® product shipments grew by <b>2.7 times</b> compared to the previous year</li> </ul>	    
	<p><b>Transport and Supply</b></p>	Real-time stable drug supply			
 <p><b>Drug Registration</b></p>	<p><b>Access Program</b></p>	Actively obtain multiple national drug approvals	<ul style="list-style-type: none"> <li>Establish marketing task forces in multiple countries and strategic alliances with external partners</li> <li>Plan short and medium-term drug approval applications around the world</li> </ul>	<ul style="list-style-type: none"> <li>BESREMi® has obtained approval from more than <b>38 countries</b></li> <li>Obtained the "pre-import license for imported drugs" for Ropeg from the Macau Pharmacology Administration</li> <li>Obtained NHI pricing in Taiwan, benefiting more local patients</li> </ul>	 

Value Chain	Issues	Strategy	Scope and Market	Impact	Correspond SDGs
 <p><b>Marketing and Sales</b></p>	<b>Academic Exchange</b>	Demonstrate medical value	<ul style="list-style-type: none"> <li>Collaborate with partners to expand <b>the social impact</b> of local biopharmaceutical industries</li> <li>Promote access to medical initiatives and sponsor related organizations and activities</li> </ul>	<ul style="list-style-type: none"> <li>Assisted in establishing <b>the first MPN treatment center</b> in Taiwan and the Taiwan Myeloproliferative Neoplasm Care Association</li> <li>Provided support for <b>five</b> major North American patient-related group activities</li> </ul>	
	<b>Fair Pricing</b>	Witness the economic value of products	Assess the value of products in different countries' medical and economic systems based on pharmacoeconomics and health technology assessments ( <b>HTAs</b> )	<ul style="list-style-type: none"> <li>Achieved legitimate and sustainable pricing strategies</li> <li>BESREMI® has been included in the <b>NCCN</b> in the United States and the <b>ELN</b> guideline in Europe</li> </ul>	
	<b>Patient Support</b>	Provide resources to remove barriers	Host multiple health education activities to enhance patient awareness of disease treatment and support patient support programs to remove medical barriers	<ul style="list-style-type: none"> <li>Taiwan <b>MPN iCare Program</b></li> <li>The patient support <b>SOURCE</b> Program in the United States</li> <li>The <b>Patient Power</b> program in the United States, patient advocacy groups and education activities for <b>MPN advocacy and education</b>, and the <b>MPN Research Foundation's</b> clinical trial search engine</li> </ul>	
	<b>Medical Contribution</b>	Reduce disparities in medical use	Provide medicine to patients with MPN through various channels and sponsor medication for <b>disadvantaged patient groups</b>	<ul style="list-style-type: none"> <li>Over <b>3,800 patients</b> have been treated with BESREMI®</li> <li>The medicine has been provided in <b>20 hospitals</b> in Taiwan to support local needs</li> <li>Sponsored BESREMI® for more than <b>500 disadvantaged patients</b> in the United States, Taiwan, South Korea, Singapore, and other places</li> </ul>	
 <p><b>Patient Safety</b></p>	<b>Pharmacovigilance</b>	Multi-channel pharmacovigilance	<ul style="list-style-type: none"> <li>Establish a mailbox for reporting adverse drug reactions and a market notification management center</li> <li>Establish a database to ensure local clinical data generation and quality</li> </ul>	<ul style="list-style-type: none"> <li>Mailbox for reports ▶ <b>5.4 Patient Safety Management</b></li> <li>Regular publication of PSUR reports for <b>real-time monitoring of drug safety</b></li> </ul>	
	<b>Product Tracking</b>	High-tech serialization of products	Implement <b>drug serialization</b> to comply with the US Drug Supply Chain Security Act regulations	<ul style="list-style-type: none"> <li>The US drug packaging plant we have partnered with implements drug packaging and serialization correctly</li> <li>Establishment of a drug traceability system for continuous monitoring of drug flow and usage records</li> </ul>	
	<b>Product Recall</b>	Recall management mechanism	Establish a <b>comprehensive product traceability mechanism</b>	<ul style="list-style-type: none"> <li><b>No drug recall incidents</b> occurred in 2022</li> <li><b>No product-related deaths</b> were reported to the FDA in 2022</li> </ul>	