



4.2 Globalizing Local Capacity Building and Access to Healthcare Material Topic

PharmaEssentia adheres to a patient-centered approach, and plans various actions and support programs to implement access to medicine and meet patients' health-related needs. Through activities such as health education, financial and medical support, academic exchanges and more, we provide patients with a comprehensive and integrated plan that covers every stage of their treatment.



Internal Policies

- HCP& HCO Interaction Policy
- Promotional Material Policy

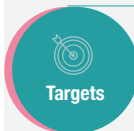
External Guidelines

- World Health Organization (WHO)
- International Research-Based Pharmaceutical Manufacturers Association (IRPMA)
- Pharmaceutical Research and Manufacturers of America (PhRMA)
- National Council for Prescription Drug Programs (NCPDP)



Implement various action plans related to patient health

- Ensure complete collection and timely reporting of safety data through multiple channels for adverse drug events in compliance with laws and regulations
- Ensure that all patients using PharmaEssentia's drugs have clear knowledge of the disease's characteristics, the effects of the drug, and treatment outcomes
- Promote disease-related knowledge as well as provide treatment consultation and referral services
- Provide health care and follow-up for patients during the treatment period
- Promote local medical care and social participation to expand PharmaEssentia's external social influence



Short-term Targets for 2023

- Implement MPN education program: Increase awareness of MPN and provide education to help patients understand the disease or get proper diagnosis and treatment, such as sponsoring the MPN Asia International Symposium and American Society of Hematology (ASH)
- Continue to promote the patient support SOURCE program to serve US patients
- Participate in local medical, educational and academic-related seminars and events to build positive connections with the local community
- Continue to collaborate with TMPNA to hold patient education activities
- Collaborate with the Chiayi Chang Gung Memorial Hospital to provide assistance for occasional health education activities
- Provide the latest health information through MPN iCARE

- Initiate clinical research and development of BESREMi[®] in the field of tumors

Medium-term Targets for 2024-2026

- Continuously promote various BESREMi[®]/Pacritinib[®] related health education activities with patient groups from different countries to give them accurate information about disease treatment
- Continuously strengthen diverse activities and stakeholder negotiations, and expand to more local medical organizations
- Promote other BESREMi[®]-related patient support programs in countries where BESREMi[®] is already on the market to comprehensively expand global coverage
- Accelerate research and development of BESREMi[®] for other MPN-related diseases, and expand BESREMi[®] to other disease treatments

- Monitor related advocacy issues around the world, and examine available resources and benefits
- Assist Taiwanese patient groups to connect with patient groups from all over the world, and share their experiences in treatment

Long-term Targets (2026 and beyond)

- Expand BESREMi[®] to all countries where it is on the market, and establish a system for giving medical care to those need it. With comprehensive care for those with rare diseases and community participation, we will enhance the company's positive contributions and influence on the global medical system for treating rare diseases and for society in general
- Assist Taiwanese patient groups to connect with international patient groups and share treatment experiences



- Marketing departments and medical affairs teams at PharmaEssentia Headquarters and our subsidiaries
- ECCS – Access to Medicine team and Product Quality and Patient Safety Taskforce



- Taiwan Patient Education Support Program, assisting the establishment of the **first MPN treatment center and the Taiwan Myeloproliferative Neoplasms Association (TMPNA)**
- An interactive **patient education platform "MPN iCare Program"** in Taiwan, providing educational information to patients and their families
- Providing Besremi[®] to medical institutions participating in clinical trials through the PharmaEssentia Can Help project
- Commissioning a professional management consulting company to set up a toll-free hotline for a medical information consultation center, notifying those in departments relevant to hospital and factory pharmacovigilance who are in charge of monitoring and quality assurance (QA). The email address for receiving drug safety reports has been announced on the company's website in Taiwan
- Establishing an electronic mailbox representing PharmaEssentia in collaboration with a drug safety research institution to receive reports on drug safety from countries where the drug is marketed



Management Evaluation Mechanism

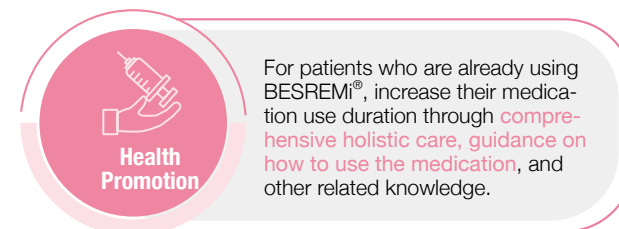
- Evaluation of the budget goals and execution of various marketing and seminar activities by the marketing departments and medical affairs task forces at PharmaEssentia Headquarters and the subsidiaries

2022 Evaluation Results

- Continuation of the operation of Taiwan's first MPN treatment center in collaboration with Chiayi Chang Gung Memorial Hospital
- Continuation of the operation of the MPN iCare platform for patient education and interaction in Taiwan
- Panco Healthcare organized four educational events and invested more than **28+ person-times** with a total participation of nearly **800 people**. One such session was to increase physicians' knowledge of MPN and the effectiveness of long-acting interferon therapy
- The "PharmaEssentia Can Help" project provides BESREMI®
- Initiated the patient support **SOURCE Program** in the United States to serve American patients
- Assisted the **Taiwan Myeloproliferative Neoplasms Association (TMPNA)** in establishing and held the first national patient education seminar in collaboration with Chiayi Chang Gung Memorial Hospital's MPN center
- Organized special blood disease education events with a total of **40 participants**
- Initiated the patient support **SOURCE Program** in the United States to serve American patients
- Sponsored the MPN Asia International Medical Symposium regularly each year, but was suspended due to the pandemic. The plan is to continue hosting physical conferences in Taiwan in 2023

Value Chain Empowerment Program GRI 413-1/413-2

PharmaEssentia's value chain empowerment program focuses on key activities and training programs for each stage of the value chain. The company has not assessed any negative impact of its operations on the local community. To improve access to medicine for patients in need of financial assistance, the company has developed initiatives. For patients already using BESREMI, a series of health promotion activities have been planned to extend their medication duration and improve overall treatment outcomes.



Capacity building programs related to the value chain

Research and Manufacturing

- **PharmaEssentia Innovation Research Center:**
Establish an innovation research center (PIRC) in Boston, Massachusetts, recruiting 25 researchers to develop a more diverse product line. Artificial intelligence and machine learning will be combined to provide information for new research targets and indications, expanding the field of disease research
- **New drug development strategy - Taiwan Biotech Academy in-person and online seminars:**
The course shares the process that takes place from new drug development to approval and marketing, development strategy, and practical problems that need to be solved. It is also hoped that after the course can stimulate more ideas for R&D ideas and pass on experiences of successful development of new drugs in Taiwan
- **2022 summer internship program:**
Combining the advantages of schools and industry practices, students will receive 1-2 months of project lectures and training before being assigned to related departments such as R&D or clinic testing for practical operations, which helps to cultivate professional talents for the biopharmaceutical industry from the source

Drug licenses application process

- **Regulatory considerations and experience-sharing on the use of overseas data in the development of new drugs in Taiwan :**
Development of new drugs in Taiwan targets the global market, and is based on R&D strategy and international collaboration; pivotal trials are often conducted overseas. This session will be about strategies on using overseas data for approval of new drugs in Taiwan

Medical education and outreach

- **Assistance in the establishment of the Taiwan Myeloproliferative Neoplasms Awareness Association (TMPNA) and the organization of health education events in collaboration with the MPN Center at Chiayi Chang Gung Memorial Hospital:**
Aimed at enhancing patient awareness and understanding of the disease and its treatment, as well as reducing information gap between patients and healthcare providers



- **Cooperation and Academic Exchange in Taiwan:**
Collaboration with the Taiwan Hematology Society and the Young Pharmacists Association to hold health education events aimed at enhancing physician knowledge of MPN and the efficacy of interferon treatment, with a cumulative attendance of over 700
- **Medical education programs in the US:**
Sponsorship of medical education programs by the US subsidiary, including conferences and on-demand educational content
- **Participation in the Patient Power Program in the US:**
Aimed at providing support to PV patients and promoting the correct information about the disease's treatment through online digital content, with over 3,200 viewings recorded. The project not only facilitates dialogue between patients and physicians, but also enhances public understanding of the disease
- **Assistance to MPN patient groups and international education events:**
Support for over 8 events for 5 major North American patient groups, including the **MPN Research Foundation**, **Canadian MPN Research Foundation**, **MPN Advocacy & Education International**, **Patient Power**, and **PV Reporter**. These events include both online events and 2 in-person events whose aim is to enhance patient knowledge and facilitate the exchange of opinions, as well as promote diagnosis of the disease, treatment goals, and related information, while also increasing awareness of the medical benefits of BESREMi among the MPN community
- **The MPN Research Foundation and Clinical Trial Search Engine in US:**
Helped establish the MPNRF clinical trial search tool, which provides a good matchmaking channel for MPN patients and their physicians. The search engine helps MPN patients and their physicians find suitable clinical trials to initiate subsequent treatment



Supply Chain Management

- **Supply Chain and Healthcare System Enhancement:**
Collaborate with external CMO companies that have obtained qualified certifications to complete the final filling of BESREMi and sell it directly to local markets, ensuring that all patients can access the medication in a timely manner

Pharmacovigilance

- **Establishment of Special Task Forces:**
PharmaEssentia has established an active drug surveillance task force with a global presence, assigning dedicated personnel in each subsidiary region and collaborating with external partners to monitor drug use safety

Data Generation and Quality Improvement

- **Data Maintenance:**
Establish dedicated medical affairs task forces and quality management task forces to handle issues related to clinical data collection, ensuring the generation and quality improvement of clinical data

Finance and Medical Assistance

- **Compassionate Use:**
Provide medical solutions to patients with severe or immediately life-threatening diseases who do not qualify for clinical trials. After internal review, compliance with regulations and ethics committees, eligible patients can apply to use experimental new drugs that have been researched but not yet approved for marketing worldwide, and start treatment courses. Currently, 40 patients around the world continue to receive medical assistance through the Compassionate Use program.
- **SOURCE Program:**
Applicable to patients using BESREMi as a prescription drug, it provides comprehensive support, including insurance information, medication-related guidance, and the process of the continued prescription of the medication. It helps provide more convenience for patients who cannot access the medication due to insurance payment delays or insufficient insurance coverage, as well as free medication for patients without insurance or has insufficient insurance coverage, aiming to provide a stable supply of Pharmigene drugs and reduce financial burden.



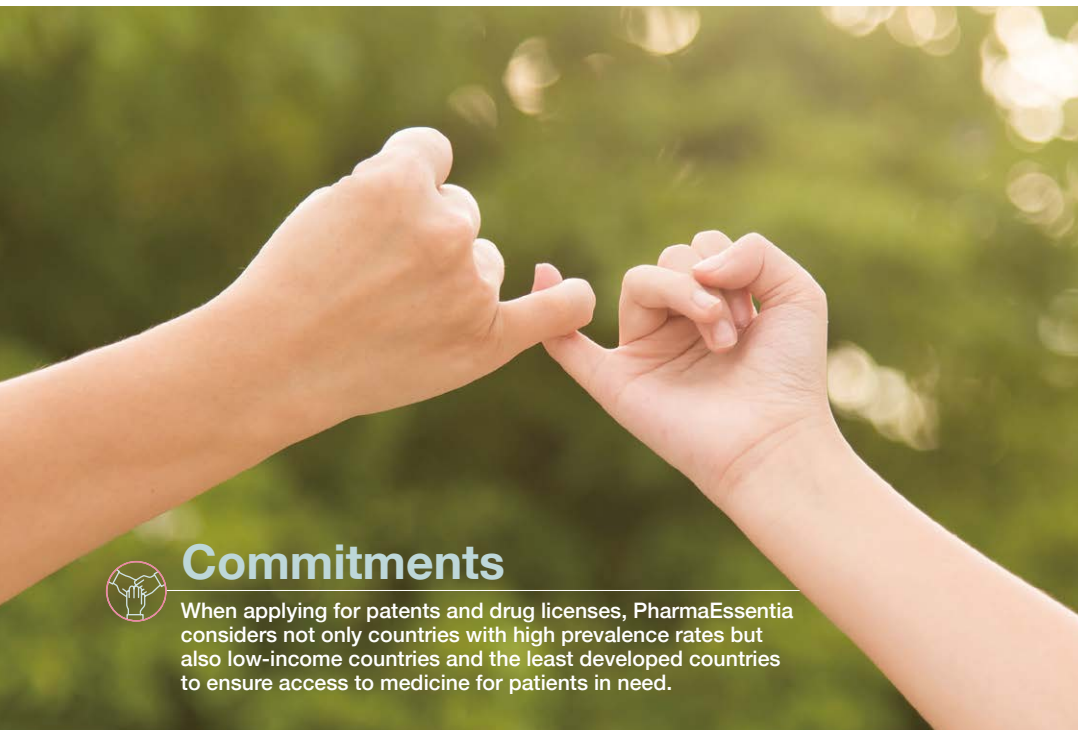
Cross-Value Chain

- **National Biotechnology Park Investment and Talent and Technology Matchmaking Conference:**
Participate in jointly organizing the National Biotechnology Research Park Investment and Talent and Technology Matchmaking Conference, including trend forums, investment matchmaking meetings, talent matchmaking, and biomedical startup exhibitions, etc., as well provide an integrated resource platform to assist biotech startup talents and task forces in accelerating the process of productization
- **2022 Taiwan Biopharmaceutical Industry Analyst Training Course:**
The course aims to cultivate professional new drug analysts, and Pharmigene was invited to jointly teach the course, with the aim of establishing a professional knowledge exchange platform for domestic finance and biotechnology industries and cultivating students as professionals in the field of biomedicine.



Intellectual Property Sharing Promotes Access to Medicine

Based on the differences in medication adherence and demand, PharmaEssentia adjusts its operational strategies when entering local markets where it has obtained patents. To prevent the penetration of intellectual property rights in the least developed countries and the reluctance of the international biopharmaceutical industry towards the right to access to medicines, not only are the countries where patent applications for important new drugs are filed investigated for the global prevalence of the new drug indications but special considerations are given to developing countries with high total demand and relatively low national income, as well as low-income countries and least developed countries, to meet the needs of patients in less advanced countries and their access to medicine. When faced with a trade-off between patent rights and humanitarian aid, medical needs are given priority, and patented new drugs are made available to patients at affordable prices and through convenient channels.



Commitments

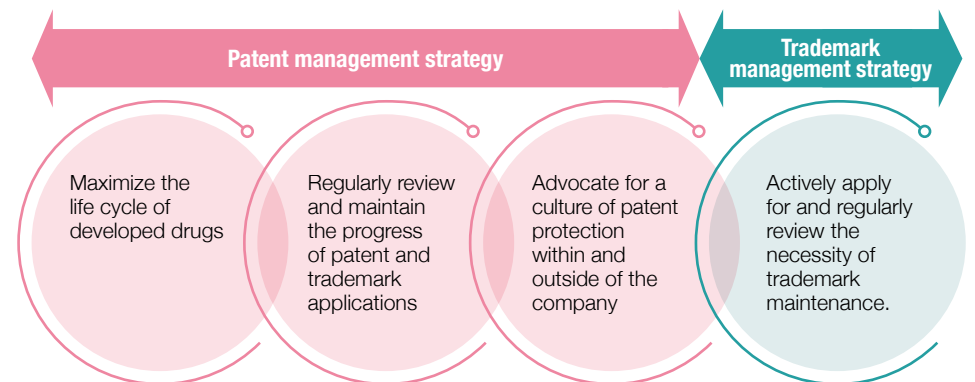
When applying for patents and drug licenses, PharmaEssentia considers not only countries with high prevalence rates but also low-income countries and the least developed countries to ensure access to medicine for patients in need.

Well-Established Patent Management and Application Policies



PharmaEssentia has formulated the "Intellectual Property Management and Utilization Measures" to regulate intangible assets such as patents, trademarks, copyrights, and trade secrets. The measures are closely linked to R&D cycle regulations and asset acquisition or disposal procedures to ensure the protection of the company's intellectual property and its widespread application and registration in the world. This allows more people in need to be informed about and have the opportunity to use new drugs.

PharmaEssentia has a strong global presence in terms of R&D patents and has proactively implemented a global intellectual property strategy for obtaining multiple country-specific drug licenses. As of 2022, the company has obtained a total of 89 (an increase of 6) valid patents in 202 sovereign countries. In addition, the company has registered 112 trademarks in 29 countries/regions, with 8 new certificates in 2022. The Intellectual Property Department reports annually to the board of directors on the implementation of the intellectual property management plan and includes the management of intellectual property in the internal control procedures, in accordance with the Corporate Governance Guidelines for Listed and OTC Companies, to ensure the protection of the company's intellectual property rights.



Technology Licensing can Maximize the Value of Intellectual Property

To accelerate the promotion of access to medicine, the company has collaborated with external partners to license its patents to others. Additionally, the company has also collaborated with pharmaceutical companies outside of Taiwan to obtain licensing for patents and technology, enabling further development and commercialization. In the future, we plan to establish a systematic management mechanism for external collaboration and technology transfer, maximizing the social value of our intellectual property management.



Out-licensing

AOP Orphan has been granted a license to market Ropeg for the treatment of rare blood disorders in Europe, the Middle East, and the Commonwealth of Independent States. In 2019, the drug received European Union marketing approval, and the company has been promoting its marketing and sales in the region.



Licensing In

- Licensing of Tirbanibulin (KX 01) from Athenex Inc. in the regions of Taiwan, Singapore, China, Malaysia, Japan, and Korea, with indications expanded to include skin cancer and all dermatologic indications.
- Exclusive licensing of the cancer drug Oraxol[®] from Athenex Inc. for sales in Taiwan, Singapore, and Vietnam, with ongoing efforts to obtain market approval in the US, Taiwan, Singapore, and Vietnam.
- Collaborating with licensing partner Axis Therapeutics on the technology transfer and clinical trials of a new TCRT-ESO-A2 cell therapy product for solid tumor treatment.



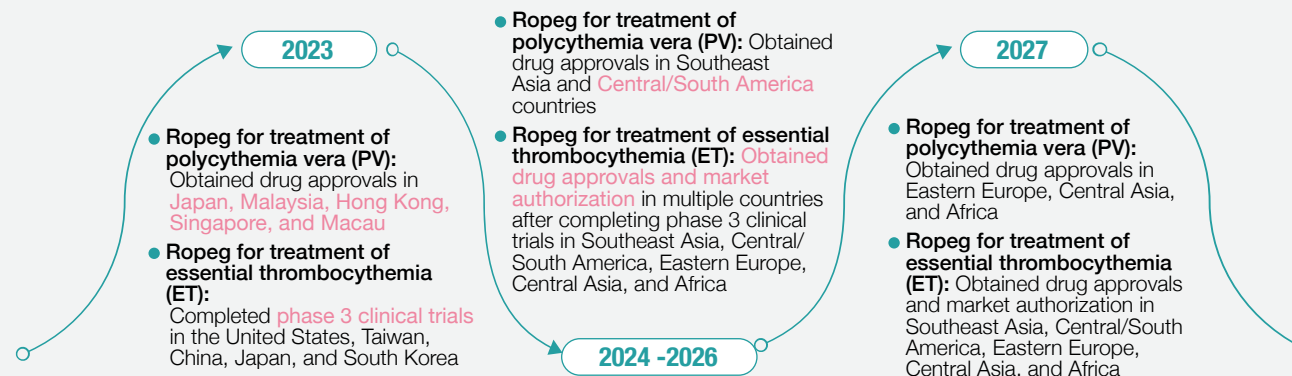
The company has obtained the exclusive rights to sell Tirbanibulin in certain regions.



The company has obtained the exclusive rights to sell Oraxol[®] in certain regions.

Short-to-Medium-Term Drug License Registration Plan

The company has successfully obtained licenses for Ropeg, a product used to treat rare blood disorders, for the treatment of polycythemia vera (PV) in over 38 countries, including the European Union, Israel, Taiwan, South Korea, and the United States, and continues to submit applications for PV licenses to other regulatory authorities. Phase III clinical trials for essential thrombocythemia (ET) are also underway in various countries, and the trial results will support the ET licensing plan, benefiting more patient communities suffering from MPN-related diseases.



Global Marketing and Market Promotion

To improve services for local patients and comply with local market regulations, in addition to AOP Orphan's responsibility for the European, Middle Eastern, and CIS markets, PharmaEssentia has deployed subsidiaries in the Asia-Pacific region and throughout the United States, and established professional marketing task forces to accelerate local market sales. In 2022, no complaints were received regarding sales activities from regulatory authorities or voluntary complaints.

European Market

30+ countries

Providing nearly a thousand patients in over 30 countries in Europe with access to treatment



BESREMI[®] sold in Europe

Available in the European Union since 2019, the drug is currently sold in more than 30 countries in Europe, with nearly 1,000 patients using the drug. In 2022, sales in Europe continued to grow and tripled from the previous year, spreading the positive influence brought by the access to the medicine.

Taiwan and Asia-Pacific Market

Sales and distribution in Asia-Pacific

Expanding sales and distribution in the Asia-Pacific region with Taiwan at the center



百斯瑞明[®] sold in Taiwan

With Taiwan as its central base, Ropeg has established professional marketing task forces in South Korea and Japan to devise marketing strategies that increase the drug's visibility and sales, ultimately providing better clinical outcomes for patients. In 2020, Ropeg's BESREMI[®] was approved by Taiwan's Food and Drug Administration for the treatment of polycythemia vera (PV), making it an official medication covered by Taiwan's National Health Insurance. In 2021, BESREMI[®] received its second drug license in Asia from South Korea's MFDS, and in 2022, it was also approved for PV treatment in Macau. As of early 2023, Ropeg has successfully passed an inspection by Japan's PMDA, and plans to obtain regulatory approvals in other Asia-Pacific regions such as China, Hong Kong, Singapore, Malaysia, and Vietnam are ongoing.

US Market

Expanding the US market penetration

Expanding market penetration and insurance coverage to benefit more patients



BESREMI[®] sold in the U.S.

Ropeg has been expanding its market penetration in the US and increasing insurance coverage to benefit more patients since BESREMI[®] was granted approval in 2021. The drug has received enthusiastic responses from US physicians and patient communities, and the US subsidiary task force has gradually expanded market penetration and increased medical insurance coverage to reach 100% and commercial insurance coverage to 85%. Promotion in leading myeloproliferative neoplasms (MPN) medical centers has exceeded 80%. To address the challenges of the US supply chain and market marketing, the task force regularly reviews the execution of injection filling, logistics, and supply chain, and actively discusses process and process optimization solutions with partners to ensure the drug's logistics and supply chain are safe and stable, and to continue expanding the US business market.