



2020
Sustainability Report

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Cover Story

The cover design pays tribute to Picasso's cubism painting style but subverts tragic and distorted elements into warm and bright colors. Moreover, the design composition lets the patient be surrounded by the scientists and medical staff in the center. It shows not only PharmaEssentia's care but our sprits to pursue innovative science and breakthroughs, which is committed to bringing patients a better life.



Preamble

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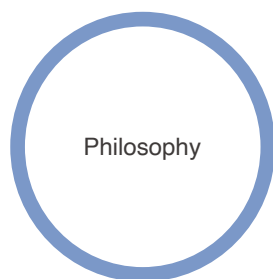
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Better science, Better lives - Purpose of PharmaEssentia Corporation

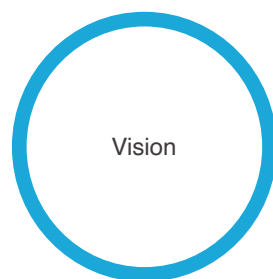
GRI 102-16

PharmaEssentia Corporation (hereinafter referred to as PharmaEssentia/ the Company) is a science-oriented company focusing on innovative biopharmaceuticals with global operations and Taiwan as its headquarters. With the philosophy of "Better science, Better lives," we commit to developing safer and more effective new drugs focusing on four major disease areas: Hematology, Oncology, Infectious Diseases, and Dermatology. We envision becoming a world-class innovative biopharmaceutical company. We aim to conduct R&D on innovative drugs with the strategies of promoting "accessibility," "affordability," and "availability," based on the philosophy of sustainable development to optimize the patients' health and well-being. To be specific, we continue to ensure the accessibility of new medicines to patients worldwide, provide medical services that meet treatment needs, and supply the products by legal and safe channels.

Furthermore, we ensure the affordability of the medicine by allowing patients to obtain it at a reasonable, fair price. Thereby achieving the strategy of helping patients in economically disadvantaged countries have access to the availability of needed drugs. To do so, we maximize the product coverage for patients globally to promote the patients' health and well-being. We also uphold a vibrant entrepreneurial spirit by maintaining our core values of bold innovation and rapid adaptation to business environmental changes making us innovative and agile. We continue to create a biopharmaceutical company that is innovative, performance-oriented, trustworthy, and respectable by patients so that we can ensure to respond effectively to stakeholders' concerns about the Company's sustainable development.



Better science, Better lives



Becoming a world class innovative biopharmaceutical company



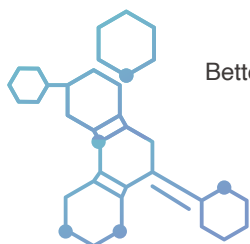
Building a new biopharmaceutical company that is innovative, performance-oriented, trustworthy and respectable by patients



Bold innovation, Rapid adaptation, Strong integrity, Sustainable development



Focusing on "accessibility," "affordability," and "accessibility" of patients to maximize human health and well-being



Major milestones

2003

PharmaEssentia was founded by a group of high-ranking scientists from leading biotechnology companies overseas.

2009

- ▶ Signed a cooperation agreement with AOP Orphan.
- ▶ Ropeginterferon alfa-2b (P1101) was approved by US FDA, and entered into phase I clinical trial.

2016

Became a TPEX-listed company.

2019

- ▶ AOP Orphan obtained the EMA marketing authorization approval.
- ▶ Athenex, an US company, authorized Oral Paclitaxel Oradoxel for the treatment of prostate cancer, approved by Taiwan TFDA for Phase I clinical trial.
- ▶ Phase II clinical trial proposal for Polycythemia Vera (PV) conducted in Japan by our Japanese subsidiary has been successfully submitted to PMDA.

A fully integrated protein innovative biopharmaceutical company

R&D of new drugs

Clinical trials

Manufacturing and production

Global sales

2005

Developed the flagship drug Ropeginterferon alfa-2b (P1101).

2012

Construction of the Taichung plant started.

2013

AOP Orphan initiated Ropeginterferon alfa-2b (P1101) phase III clinical trial.

2018

- ▶ The Taichung plant obtained an EU GMP license certification.
- ▶ Initiated mass production for commercialization.
- ▶ AOP Orphan released Ropeginterferon alfa-2b (P1101) phase III clinical trial results at the annual meeting of American Society of Hematology.

2020

- ▶ 百斯瑞明® obtained approval letter from TFDA.
- ▶ Successfully submitted Biologics License Applications (BLA) of Ropeginterferon alfa-2b (P1101) to US FDA.
- ▶ Successfully submitted Biologics License Applications (BLA) of Ropeginterferon alfa-2b (P1101) to Korea MFDS.
- ▶ The sterile filling plant has been approved by Taiwan TFDA GMP and GDP.
- ▶ A international phase III clinical trial of ET has been initiated in the United States, China, Japan, South Korea, Taiwan and Hong Kong.
- ▶ Ropeginterferon alfa-2b (P1101) for the treatment of chronic hepatitis B or chronic hepatitis B combined with hepatitis D has been approved by Taiwan TFDA for Phase Ib clinical trial.

2.

PharmaEssentia's Recent Awards and Honors

2020

Won the Gold Medal of Go-Global category in 2020 Taipei Biotech Award.



2019

Awarded with the "2019 Innovative products of excellent manufactures in Central Taiwan Science Park Award" for Ropeginterferon alfa-2b (P1101) (product name: 百斯瑞明®).

2019

Awarded with the "Gold Award in the Pharmaceutical Category" of the "2019 Pharmaceutical Research and Development Award from Ministry of Health and Welfare and Ministry of Economic Affairs" for Ropeginterferon alfa-2b (P1101) (百斯瑞明®) — new generation of long-acting interferon.

2019

Chief Executive Officer, Ko-Chung Lin, was awarded the "Humanitarian Award" from the Cancer Research & Treatment Fund. He is also the first Asian to receive this award.

2019

Awarded with the "Taiwan Merck Advance Biotech Grant — Emerging Biotech Second Prize."

2018

Awarded with the "11th International Congress on Myeloproliferative Neoplasms — Award for Outstanding Commitment to Hematologic Oncology."

2018

Awarded with the "Winner for Bioprocessing Innovation in Oncology Drug Development Pipeline in Taiwan" for "2018 Excellence Award for Bioprocessing in Asia-Pacific Region."

2017

Awarded with the "Winner for Development of Novel Pegylation Platform Technology" for the "2017 Excellence Award for Bioprocessing in Asia-Pacific Region."

3.

Messages from the management team

GRI 102-14

Chairman Ching-Leou Teng:

Stay true, continue to deepen the sustainability gene.



PharmaEssentia Corporation's vision is "Better Science, Better Lives." Alleviate the pain and bring a better life for all humankind through scientific R&D of new drugs." We look forward to using the power of science to bring hope to patients and their families, as well as bringing change to the world. We take the patients' welfare as the core value, standing at the forefront of medical technology to seek innovative biological drugs and providing high-quality medicines with correct, ethical, transparent, and adequate information. We continue to make a name for ourselves in the global pharmaceutical industry by supporting the healthy lives of people around the world.

In the second sustainability report, published in 2021, we introduced "SMART: Specific, Measurable, Attainable, Relevant, and Time-based" as the management principle to set our goals. Putting environmental (E), social (S), governance (G) (hereinafter referred as ESG) as short-term, mid-term, and long-term sustainability goals for highly significant topics which allow us to thoroughly examine the systems of the Company and take responsibility for the effective allocation of resources to promote sustainable corporate development. For the first time, we used the Enterprise Risk Management (ERM) framework jointly published by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and the World Business Council for Sustainable Development (WBCSD) to consider the likelihood and impact level of the risk events based on significant ESG topics. The identification of our non-financial risk topics in ESG enables us to more precisely and effectively manage the potential risks faced by the Company in a constantly changing environment, and to enhance our competitiveness and corporate resilience, in order to continue to create more opportunities for business development.

Looking ahead, under our strategy of globalization and continuous development of innovative drugs, we will create a stable and talent-motivating environment for our top three stakeholders: employees, patients, shareholders, and investors, to recruit talents in biopharmaceutical R&D and various professional fields to develop the high-quality

new drugs with the best technology and the highest quality control. In addition, we hope that by continuously improving our sustainability values to achieve the three significant aspects of ESG, gain the favor of foreign institutions, and find more partners in the capital market who recognize our philosophy of sustainability. We are working together to address unmet medical needs around the world, to explore and develop potential new medicines and technologies, and to provide affordable and accessible medicines to patients, in keeping with our commitment to "access to medicine." Finally, in the face of the global climate emergency shared by all humankind and the call for companies to face up to the climate crisis and formulate actions in response, we will implement ISO 14064-1: the greenhouse gas inventory verification in 2021, after this, PharmaEssentia will set a carbon reduction target to mitigate climate change and overcome the climate crisis together with all humankind. We will together protect the Earth and become a biopharmaceutical company that stakeholders can trust and respect. We also cordially invite you to read this sustainability report and give us valued advice and suggestions. Thank you!

Chairman

A handwritten signature in black ink that reads "Ching-Leou Teng".



CEO Ko-Chung Lin:

People-oriented, root in Taiwan and look ahead to the world

2020 was a year full of uncertainty, with the outbreak of COVID-19, wildfires in the western United States, Siberia, and Australia, a volatile political and economic situation, and human rights topics, once again reflecting the insignificant and helplessness of human beings. And yet, as we move through the challenging year, we can still see the human values of global citizenship and mutual goodwill. These ESG-related impacts did not end in 2020 but will continue to affect situations in 2021 and beyond. Citizens worldwide must still come together to confront the ever-present crisis of infectious diseases, the climate emergency, and the volatile world situation.

In the challenging year of 2020, we are fortunate to have the concerted efforts of our global colleagues, and we independently developed an innovative new generation of long-acting interferon, Ropeginterferon alfa-2b (P1101). After obtaining the EU approval for the treatment of Polycythemia Vera (PV) in 2019, it has been launched in

various countries by the end of 2020, including approval by Switzerland, Liechtenstein, and Israel, etc. Otherwise, only except for the European business partner AOP Orphan's launch under the trade name BESREMI®. In Taiwan, the Company has also obtained TFDA drug certification under the trade name 百斯瑞明®, which benefits the treatment of patients with PV. The Company's Taichung manufacturing plant has obtained Taiwan TFDA GMP certification, EU EMA GMP certification, and the South Korean Ministry of Food and Drug Safety (MFDS) GMP inspection result was acceptable. It is expected to obtain the South Korean Medicine Certificate in the second quarter of this year. Ropeginterferon alfa-2b (P1101) is used to treat PV in South Korea and the United States and has passed the orphan drug designation (ODD). Our local U.S. contracted filling foundry has also completed the U.S. FDA pre-approval inspection of new drugs. It is prospected to obtain the U.S. marketing certificate for the products as the pandemic is easing, allowing the U.S. FDA to inspect the manufacturing plants in Taiwan.

In addition to the application in PV, we will continue to expand the clinical application of Ropeginterferon alfa-2b (P1101) to take advantage of the "one drug for multiple indications." The phase III clinical trial Ropeginterferon alfa-2b (P1101) for Essential Thrombocythemia (ET) was initiated in Taiwan, Japan, South Korea, China, and the United States. It is expected that after the completion of phase III clinical trial, a drug license for the treatment of

ET will be applied to the competent authorities. Through our global strategic approach, we will not only actively promote global marketing strategies and action plans for our new drug products but also consider licensing-out and licensing-in patents and technologies to maximize our new drug product lines and patient coverage of each new drug in the global market, ensuring access to medicine for patients worldwide.

As the world enters a new normal in the post-pandemic era in 2021, the valuable experience we accumulated through each year and stage since our establishment will enable us to overcome future challenges positively, courageously, and firmly and achieve sustainable corporate resilience. As an international innovative biopharmaceutical company that strives to integrate all stages of development from new drug R&D, preclinical animal testing, human clinical trials, manufacturing, drug license application, product launch, and market entry, we hope to become an international pioneer of new biopharmaceuticals in the Pan-Asian world. This is a path rarely traveled by biopharmaceutical companies in Taiwan. We are not going to be the only leader in Taiwan. Still, we aim to promote the upgrading and growth of Taiwan's biotech and pharmaceutical industry and promote the biotech hub Clustering effect in Taiwan. We together show our brilliance on the world stage.

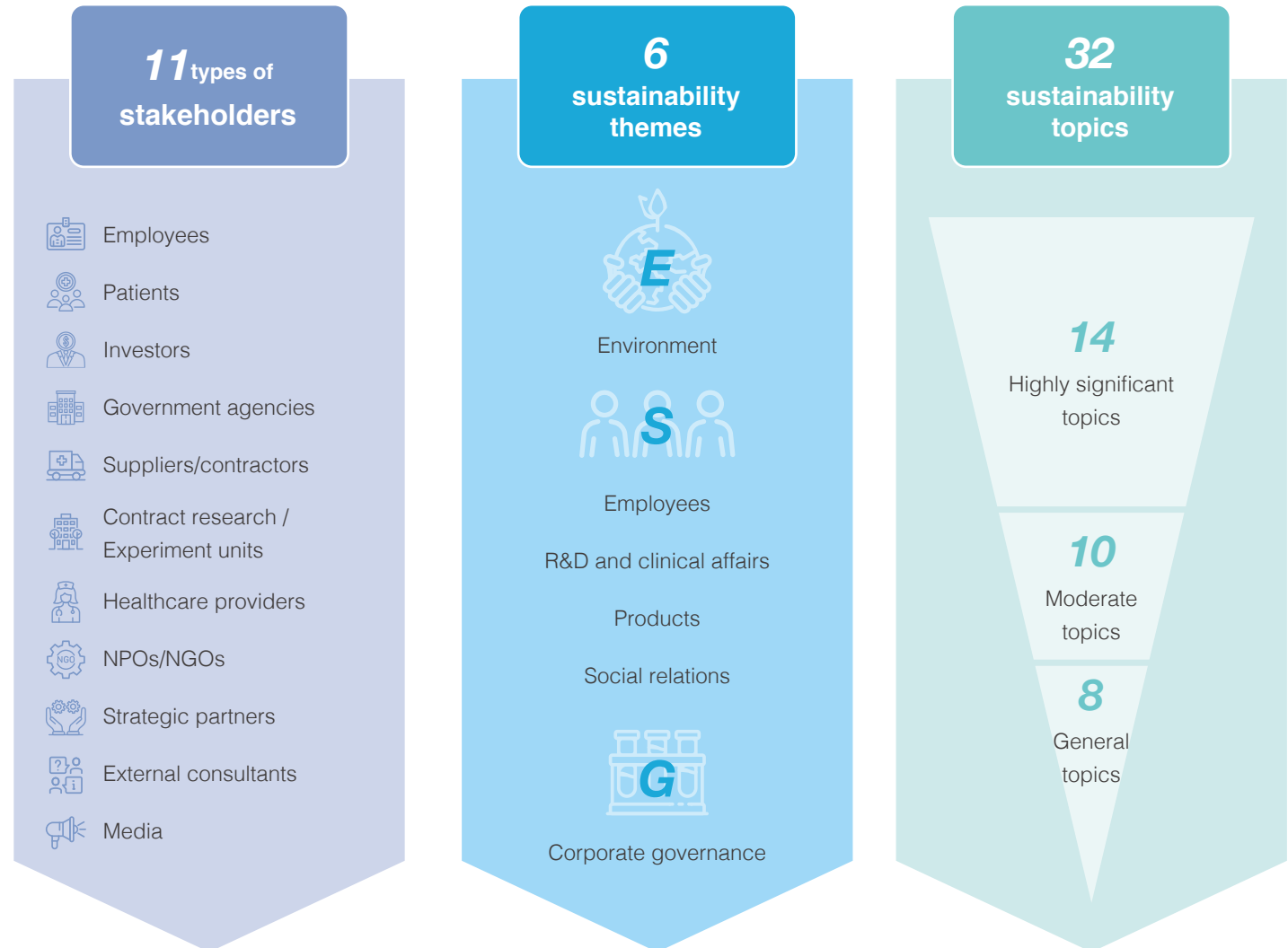
CEO

4.

Our Identification process of sustainability topics

GRI 102-46

2020 is the year of implementation revision for the Company's second step towards sustainability. We continue to implement the five-year sustainable development plan and sustainability topics planned in the first year of sustainability. We identified 11 types of stakeholders, 6 sustainability themes, and 32 sustainability topics through a complete identification process of the biopharmaceutical industry and the value chain associated with our operations, followed by a matrix analysis of stakeholder concerns and impact on the Company. The 32 sustainability topics were re-examined to rank 14 highly significant topics, 10 moderate topics, and 8 general topics. We further analyze and clarify the significance of these identified stakeholders and sustainability topics to the Company and use the six report qualities defined by the GRI International Disclosure Standards to disclose our management and communication practices. Also, we set up short-, mid-, and long-term sustainability goals and we will continuously track and improve.



Identification process of sustainability topics



1

Collection of topics

To ensure that the compilation of this sustainability report complies with the principle of inclusiveness, we first extensively collect the United Nations Sustainable Development Goals (SDGs), sustainability-related topics regarding international benchmarking standards and trends, sustainability trends in the biotechnology and medical industry, sustainability practices of benchmark companies in the same industry, and social concerns. In addition, we also draw department interview outlines to understand the Company's actual situation and management strategy.



2

Interviews focus

Based on the characteristics and business situations of each department, we formulated different sustainability interview outlines. We learned about the actual actions taken in each department and the stakeholders involved from the interview process. A total of 66 representatives of various departments participated in the department interview. The representatives include Chairman, CEO, President, COO, and Chief Medical Officer.

E Environment

1. Environment of PharmaEssentia

- ① Waste management
- ② Toxic chemicals management
- ③ Energy management
- ④ Greenhouse gas emissions
- ⑤ Water resources management
- ⑥ Biodiversity

3. R&D and clinical affairs of PharmaEssentia

- ⑳ Innovative drugs research and discovery
- ㉑ Clinical trials ethics
- ㉒ Animal welfare

S Society

2. Employees of PharmaEssentia

- ⑦ Occupational health and safety
- ⑧ Talent cultivation and career development
- ⑨ Compensation and benefits
- ⑩ Human rights
- ⑪ Work-life balance

4. Products of PharmaEssentia

- ㉔ Patient safety
- ㉕ Product quality and safety management
- ㉖ Stable and secure supply chain
- ㉗ Product marketing and labeling
- ㉘ Manufacturing process continual improvement

G Governance

6. Corporate governance of PharmaEssentia

- ⑫ Compliance and business ethics
- ⑬ Corporate governance
- ⑭ Risk management
- ⑮ Data privacy and cybersecurity
- ⑯ Intellectual property rights
- ⑰ Corporate strategy
- ⑱ Partner relations
- ㉑ Sustainable investment attraction
- ㉒ Succession plan

5. Social relations of PharmaEssentia

- ㉓ Access to medicine
- ㉔ Social contributions
- ㉕ Promote Taiwan's industrial upgrading
- ㉖ Regulatory amendments advocacy



3

Screening and analysis

We design a survey based on materiality analysis tools, which are divided into two types. The first type is for stakeholders, ranking the importance of sustainability topics according to the concerns of the stakeholders. The second type is for senior management. They are required to rank the importance of sustainability topics according to their impact on the Company's external environment, economics, and society. The survey for senior management could also assign weighted scores for the 6 sustainability themes to highlight the voice of key stakeholders.

- ▶ 5 Senior management questionnaires: Chairman, President, CEO, COO and Chief Medical Officer, 5 persons in total.
- ▶ 198 stakeholder questionnaires: The department heads acted as representatives to answer the questionnaire on behalf of the stakeholders.

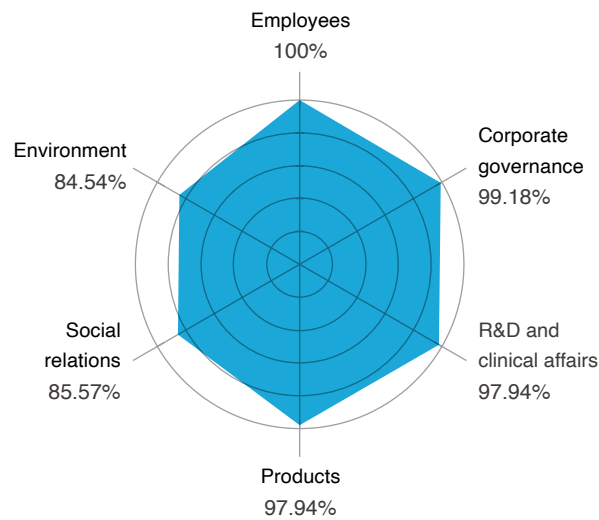


Fig1: Weighting of sustainability themes



4

Results

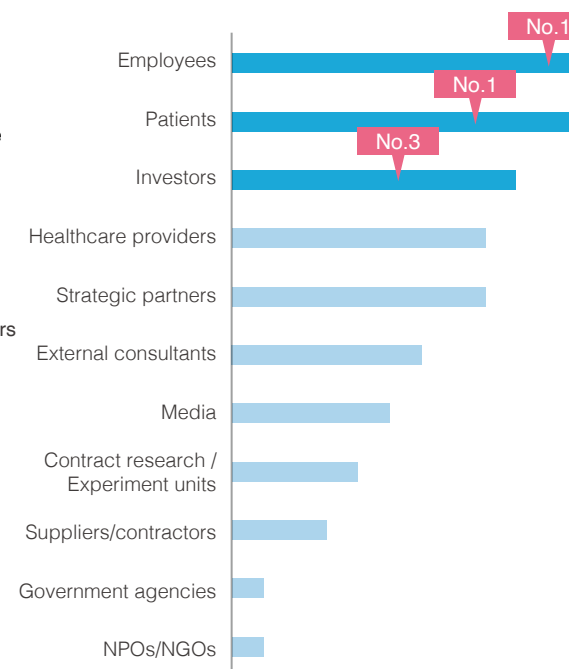


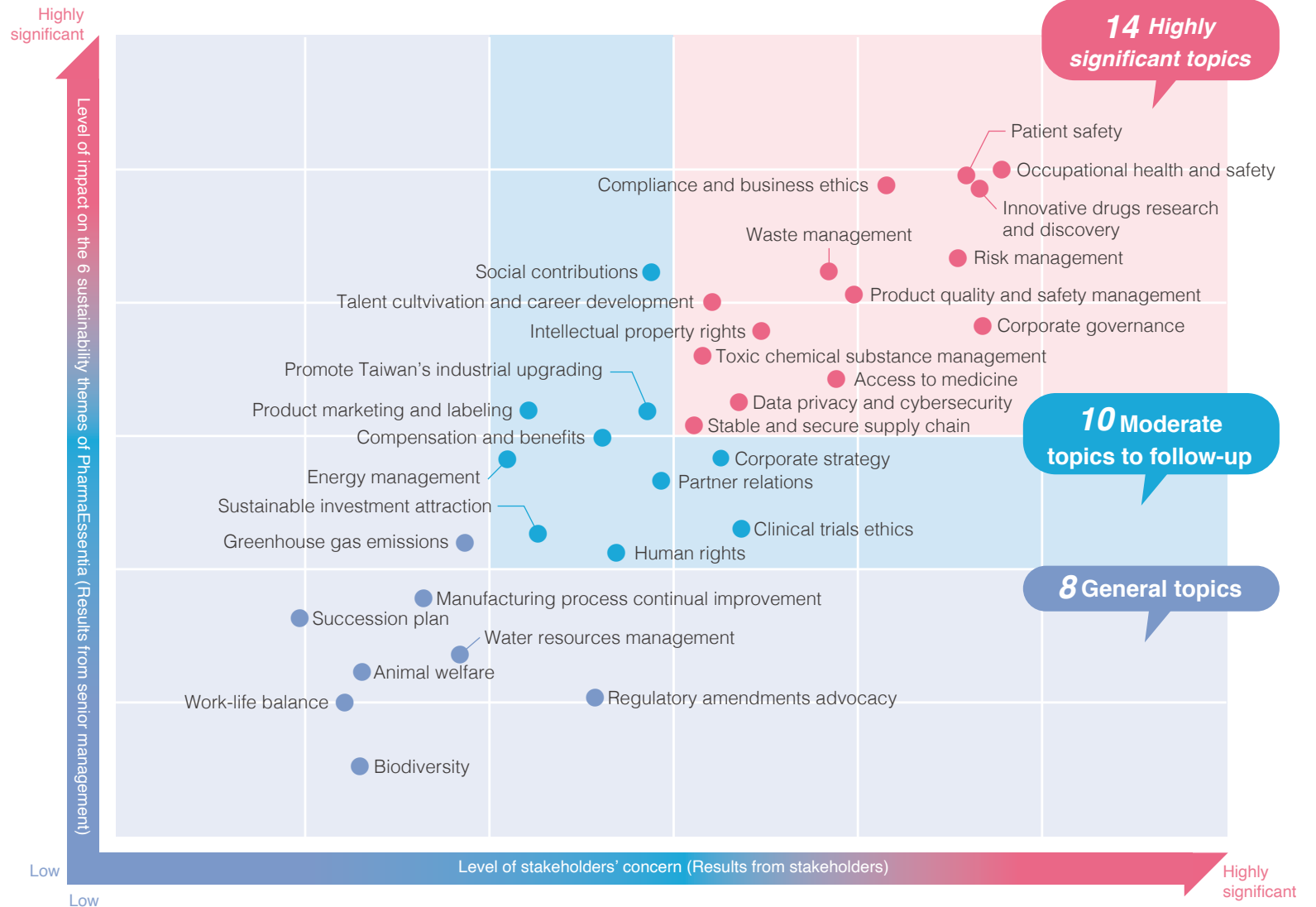
Fig2: Weighting of stakeholders

The survey results were taken into account at the Executive Center for Corporate Sustainability's meeting. Based on the Company's future strategic development goals and the progress of obtaining the listing licenses in many countries, we reviewed the analysis and results of sustainability topics. We identified the three most important stakeholders of PharamaEssentia as employees, patients, shareholders and investors. The sustainability topics include 14 highly significant topics, 10 moderate topics, and 8 general topics.

Materiality matrix in the second year of sustainability implementation

GRI 102-47

PharmaEssentia's materiality matrix is presented as below. From the two dimensions of the materiality matrix, we determine highly significant, moderate, and general topics based on the cross-results analysis. This report focuses on the 14 highly significant topics identified through the analysis, explains the importance of the topics to PharmaEssentia, and fully discloses the management policy and performance information. We will continue to conduct follow-ups and management on other topics.



The importance of sustainability topics

GRI 102-49

GRI 103-1

To allow stakeholders to have a better understanding of the 14 highly significant topics, we based on disclosure items of “Global Reporting Initiative Standards” (hereinafter referred as “GRI Standards”) to compile relevant information into the following table to illustrate the significance and impact of each topic on PharmaEssentia. Some sustainability topics are exclusive to the Company after review, identification, and analysis. There are also industry-specific topics regarding the biotechnology and biopharmaceutical industry and the Company’s fully integrated business model. We also refer to the sustainability indicators for ESG information disclosure developed by international sustainability rating organizations (Sustainalytics, MSCI, etc.), which apply to the characteristics of the global biotech industry, as a way to disclose such topics. (The topics marked with a ★ in the table below are exclusive and industry-specific topics of PharmaEssentia)

Sustainability Themes	Topics	Significance to PharmaEssentia	Corresponding GRI Principals
Employees	1. Occupational health and safety	Health and safety of PharmaEssentia employees and other workers, including interns, apprentices, suppliers, etc., in the work environment.	GRI 403: Occupational Health and Safety 403-3 403-5 403-7 403-9~10
	2. Talent cultivation and career development	Provide systematic employee training, assist employees in improving their professional skills, and cultivate critical talents in the Company and the biotechnology and pharmaceutical industry.	GRI 404: Training and Education 404-1 404-3
Governance	3. Data privacy and cybersecurity	Management mechanisms to deal with cybersecurity risks and privacy protection measures have been conducted.	GRI 418: Customer Privacy 418-1
	4. Compliance and business ethics ★	As we continue to launch multi-center clinical trials in multiple countries and progress towards obtaining multinational drug licenses, we must comply with local market regulations in each country and strictly enforce ethical behavior at all levels of the product value chain, with integrity as our highest guiding principle.	★ Industry-exclusive topic
	5. Corporate governance	The mechanism to guide and manage the enterprise, and bring advantage and mitigate disadvantages of the Company.	GRI 102-18: Corporate governance
	6. Risk management	Assess the existing and potential risks in the business process, and formulate risk management procedures and countermeasures.	GRI 102-15: Key impacts, risks, and opportunities
R&D and clinical affairs	7. Intellectual property rights ★	Manage the Company’s intellectual capital and cooperate with the Company’s R&D progress to ensure that R&D results are fully protected.	★ Industry-exclusive topic
	8. Innovative drugs research and discovery ★	Continue to explore and develop possible new drugs and technologies and enhance the innovative R&D capabilities of PharmaEssentia for unmet medical needs.	★ Industry-exclusive topic

Sustainability Themes	Topics	Significance to PharmaEssentia	Corresponding GRI Principals
Products	9. Patient safety ★	Implement drug safety monitoring in the clinical stage, establish an effective quality management system, and submit drug safety reports regularly. Establish an immediate adverse drug reaction notification mechanism for marketed drugs.	★ Industry-exclusive topic
	10.Product quality and safety management ★	Comply with "PIC/S Good Manufacturing Practice" (hereinafter referred to as "GMP") and other related regulations to ensure the safety and effectiveness of the drug life cycle.	★ Industry-exclusive topic
	11.Stable and secure supply chain ★	To ensure that the products delivered to patients are safe, high quality, and available promptly so as not to delay the optimal treatment of patients, we strive to establish a stable and secure product supply chain through a series of processes such as identifying market demand, production scheduling, quality control, drug transportation and storage, and drug traceability or tracking.	★ Industry-exclusive topic
Social relation	12.Access to medicine	Combined with PharmaEssentia's philosophy of "Better science, Better lives," it establishes PharmaEssentia's "Access to Medicine Guidelines" and sets the direction for promotion, including reasonable drug pricing, reliable drug supply, and the implementation of compassionate use, etc.	GRI 203: Indirect Economic Impacts 203-1
Environment	13.Waste management	Total amount of general waste and hazardous waste produced by PharmaEssentia, pollution prevention, and treatment methods.	GRI 306: Effluents and Waste 306-2~3 306-5
	14.Toxic chemical substance management ★	Particular chemical substances and toxic chemical substances used by PharmaEssentia laboratories and factories, and the management methods.	★ Industry-exclusive topic

Note 1. 14 highly significant topics have been developed with a management approach, which are the critical disclosures in this report.

Note 2. Because our self-developed Ropeginterferon alfa-2b (P1101) will be licensed for the treatment of PV in many countries in 2020, and it is expected to be used in multi-country and multi-center clinical trials in the future. After the successful passage of the phase III trial, Ropeginterferon alfa-2b (P1101) was expected to obtain the drug certificate for the treatment of myeloproliferative neoplasms (MPN) related diseases in various countries. Therefore, two new highly significant topics were added this year: " Compliance and business ethics " responds to the dynamics of our strict compliance with local market regulations, and " Stable and secure supply chain " responds to how we ensure that the products delivered to patients are safe, high-quality and can be provided promptly.

Note 3. The Company's " Corporate strategy " has become mature and stable, so it was adjusted to a moderate topic in 2020.

Note 4. The former "Toxic chemicals management" highly significant topic was renamed "Toxic chemical substances management."

The impact of highly significant topics on the value chain

GRI 103-1

We also review and identify topics with sustainable influences in the biopharmaceutical industry value chain and precisely analyze the impact of 14 highly significant topics on each stage of the value chain. Through this analysis, we will be able to understand better the influence of PharmaEssentia's highly significant topics in all aspects and to reinforce our sustainable management ability. The table of the impact of each highly significant topic on each link of the value chain is as follows.

Highly Significant Topics	Value chain						Corresponding Chapter
	Innovative drugs discovery	Preclinical study	Clinical trial	Manufacturing and production	Innovative drugs registration	Marketing and sales	
Innovative drugs research and discovery	●	●	●				1.3 R&D of new biopharmaceuticals
Corporate governance	●	●	●	●	●	●	2.1 Sustainable governance and development goals
Compliance and business ethics	●	●	●	●	●	●	2.2 Corporate governance and management
Risk management	●	●	●	●	●	●	2.4 Risk management
Data privacy and cybersecurity	●	●	●	●	●	●	2.5 Rigorous data privacy and cybersecurity
Intellectual property rights	●	●	●	●	●	●	2.6 Comprehensive management of intellectual property rights
Product quality and safety management			●	●	●	●	3.3 Ensuring the quality and safety of drugs
Stable and secure supply chain				●	●	●	3.1 Construct a complete supply chain system
Patient safety			●			●	3.6 Effective pharmacovigilance and recall mechanism
Occupational health and safety	●	●		●			4.5 Occupational health and safety
Talent cultivation and career development	●	●	●	●	●	●	4.4 Talent training and career development
Waste management	●			●			5.2 Waste management
Toxic chemical substance management	●			●			5.3 Toxic chemical substance management
Access to medicine	●	●	●	●	●	●	6.1 Access to medicine strategies

● = The topic impacts this stage of the value chain.

5.

Identification of Stakeholders

GRI 102-40

GRI 102-42~44

To understand the stakeholders that affect and are affected by PharmaEssentia in the course of its operations, we summarized 11 categories of stakeholders that are closely integrated with the processes from interviews with various departments. The main communication channel is the contact window of all relevant stakeholders. We will also utilize communication channels regularly to communicate on ESG topics that are of concern to all stakeholders.

Significance of stakeholder to PharmaEssentia

Stakeholders	Meaning to the Company	Topics of concern	Communication channel and frequency of communication
Employees	Employees are the most precious asset of an enterprise, especially for PharmaEssentia. The loyalty and retention rate of employees to the Company directly impact the R&D of new drugs. We hope that our present or future employees can grow together with PharmaEssentia in a lovely and happy working environment.	<ul style="list-style-type: none"> Compliance and business ethics Occupational health and safety Talent cultivation and career development 	<ul style="list-style-type: none"> Welfare committee: quarterly Compensation committee meeting: quarterly Employee convention: annually Phone calls or face-to-face interviews: when necessary Internal website: occasionally
Patients	Patients are our most direct and vital stakeholders in creating product value. The patient's health is the ultimate goal of the existence of PharmaEssentia. How to give patients easy access to medicine is our most significant concern.	<ul style="list-style-type: none"> Data privacy and cybersecurity Product quality and safety management Stable and secure supply chain Patient safety Access to medicine 	<ul style="list-style-type: none"> Sales meetings: bi-weekly Visits or conference calls: when necessary Seminar: occasionally Phone calls or E-mails: anytime
Investors	An extended period of capital investment is required before a new drug is marketed. Therefore, the trust and support of our shareholders and investors are essential. Therefore, PharmaEssentia is committed to improving its information transparency so that shareholders and investors can grasp the information of PharmaEssentia in real-time and with accuracy.	<ul style="list-style-type: none"> Innovative drugs research and discovery Compliance and business ethics Risk management Corporate governance Access to medicine 	<ul style="list-style-type: none"> Shareholders' meeting: annually Extraordinary shareholders' meeting: occasionally Board meeting: quarterly Special board meeting: occasionally Investor conference: when necessary Spokesperson: anytime Company website: occasionally Taiwan Stock Exchange Market Observation Post System: when necessary
Healthcare providers	Healthcare providers are the stakeholders closest to the patient. Their understanding of patients and their medication expertise can boost PharmaEssentia's chances of success in new drug R&D and benefit more drug users. They are also the closest partners of PharmaEssentia around the world.	<ul style="list-style-type: none"> Compliance and business ethics Access to medicine 	<ul style="list-style-type: none"> Correspondence: when necessary Seminar: occasionally Phone calls or E-mails: anytime Conference calls: when necessary

Stakeholders	Meaning to the Company	Topics of concern	Communication channel and frequency of communication
Strategic partners	PharmaEssentia's global layout needs the support of strategic partners from all over the world to enter foreign markets. PharmaEssentia's communication targets are in-licensing and out-licensing partners. We maintain close cooperation with strategic partners and achieve mutual benefit and win-win results.	<ul style="list-style-type: none"> • Corporate governance • Intellectual property rights • Stable and secure supply chain 	<ul style="list-style-type: none"> 👤 Visits or conference calls: when necessary ✉️ Phone calls or E-mails: anytime
External consultants	PharmaEssentia has made its page in the history of new drug R&D in Taiwan due to our love of learning and innovation. Therefore, we continue to internalize and integrate our profession with the help of external consultants to enhance the driving force for the growth of PharmaEssentia.	<ul style="list-style-type: none"> • Corporate governance • Risk management • Access to medicine 	<ul style="list-style-type: none"> 👥 Sales meetings: bi-weekly 👤 Visits or conference calls: when necessary 📊 Seminar: occasionally ✉️ Phone calls or E-mails: anytime
Media	In the era of multimedia and the Internet, in addition to the active communication channels of PharmaEssentia, it is necessary to communicate with many stakeholders and rely on the communication power of domestic and foreign media to accumulate the trust of stakeholders. Therefore, we maintain a good relationship with the press.	<ul style="list-style-type: none"> • Compliance and business ethics • Corporate governance 	<ul style="list-style-type: none"> 📰 Media gathering: annually 📰 News release: occasionally 🎤 Exclusive interview: when necessary 👤 Spokesperson: anytime 🌐 Company website: occasionally 📊 Taiwan Stock Exchange Market Observation Post System: when necessary
Contract research/ Experiment units	The topic selection in the early stage of new drug R&D relies heavily on the academic R&D of research units. Therefore, we support many universities to conduct research on drugs and to develop new applications. Each research result is a step towards human happiness. In addition, most of the Company's animal experiments are outsourced.	<ul style="list-style-type: none"> • Innovative drugs research and discovery • Compliance and business ethics 	<ul style="list-style-type: none"> ✉️ Correspondence: when necessary 📊 Seminar: occasionally ✉️ Phone calls or E-mails: anytime 👤 Conference calls: when necessary
Suppliers / Contractors	The raw materials, calibration services, contract manufacturing, and plant engineering required for the product life cycle rely on stable and reliable suppliers/contractors to fully implement the concept of access to medicine.	<ul style="list-style-type: none"> • Stable and secure supply chain • Occupational health and safety 	<ul style="list-style-type: none"> 👥 Production-marketing meetings: bi-weekly 👤 Visits: when necessary 🔍 On-site audit: annually ✉️ Phone calls or E-mails: anytime 👤 Conference calls: when necessary
Government agencies	The government's support for the industry is an essential helping hand. With the support from National Development Fund, PharmaEssentia has achieved stable results in the early stage of development. Nonetheless, the government's regulations and standards for the pharmaceutical industry are relatively strict, such as environmental protection. PharmaEssentia must pay close attention to the adjustment of relevant laws and regulations to avoid impairment of the rights or interests of interested parties due to violation of the law.	<ul style="list-style-type: none"> • Corporate governance • Risk management • Compliance and business ethics • Waste management • Toxic chemical substance management • Patient safety • Product quality and safety management 	<ul style="list-style-type: none"> ✉️ Correspondence: when necessary 📊 Seminar: occasionally ✉️ Phone calls or E-mails: anytime 👤 Conference-calls, charity events, or work-study programs: when necessary
NPOs / NGOs	Non-profit organizations are our good partners in implementing access to medicine. They assist PharmaEssentia in identifying patients who need drugs most but have difficulty in obtaining them. Through donation or charity, patients can have the opportunity to continue to use the medications they need to maintain their lives.	<ul style="list-style-type: none"> • Access to medicine • Stable and secure supply chain 	<ul style="list-style-type: none"> ✉️ Correspondence: when necessary 📊 Seminar: occasionally ✉️ Phone calls or E-mails: anytime 👤 Conference calls: when necessary



Chapter 1

Innovation

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Chapter 1

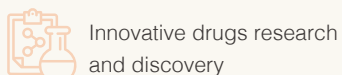
Innovation

Summary of Chapter 1

Highlights of 2020



Relevant material topics



Relevant stakeholders



Patients



Strategic partners



Investors



Contract research/
Experiment units

The original intention of PharmaEssentia was to use our new drug products to solve the suffering of patients and promote the health and well-being of all humankind. Under this corporate mission, the purpose and reason for the Company's existence are to continue to provide innovative and reliable medicines. Based in Taiwan, we invest in our in-house development of new pharmaceutical products from research and development, manufacturing, to commercialize globally. We have successfully developed a new generation of long-action pegylated interferon drugs based on the original protein drug R&D "PEGylation technology platform." The Taichung manufacturing plant has also obtained a GMP certification from EU EMA and Taiwan TFDA, and the South Korea MFDA GMP Inspection Result was Acceptable. It is expected to receive the South Korean marketing authorization approval in the second quarter of this year. Our global strategies are through "establishing foreign subsidiaries" and "partnering in-licensing, out-licensing and development," recruiting about 270 outstanding talents from all over the world, devoting themselves to innovative science and focusing on the rare hematological diseases, such as Myeloproliferative Neoplasms

(MPN), an unmet medical need. Following our "in-house developed a new generation of long-action pegylated interferon "Ropeginterferon alfa-2b (P1101)", we obtained the first EMA marketing authorization approval for the treatment of Polycythemia Vera (PV) (drug name BESREMi®) with our partners in 2019, going further to obtain Taiwan's marketing authorization approval (drug name 百斯瑞明®) in 2020. To date, we have received marketing authorization approval for using this drug in patients with PV in nearly 20 countries around the world. We also expect that the U.S. FDA will visit Taiwan as soon as the pandemic slows down. We anticipate that South Korea and the U.S. will obtain marketing authorization approval of the Biologics License Application (BLA) for the drug shortly. Other Asian countries such as Japan and China will also submit for approval later. In addition, Ropeginterferon alfa-2b (P1101) for treating ET has also been conducted in phase III clinical trials in many places worldwide. This product is expected to be used to treat other patients and fulfill our aim of R&D and manufacturing base in Taiwan, gradually entering the international market with fruitful results.

Performance highlights

First company in Taiwan

A fully integrated protein biopharmaceutical company.

International GMP-certified manufacturer

The first protein new drug plant to be approved with the EMA inspection and validation. The Filling Plant has also obtained Taiwan TFDA GMP and GDP certification and the South Korean MFDS's GMP inspection result was acceptable. It is expected to obtain South Korean marketing authorization approval in the second quarter of this year.

The global phase III clinical trial of ET is fully launched.

Ropeginterferon alfa-2b (P1101) for ET treatment in phase III clinical trials has been conducted in many places around the world.

Thousands of patients in nearly 20 countries around the world using this drug

BESREMI® has successfully obtained marketing authorization approval in many countries in Europe and Asia.

270+ high-quality talents around the global territorial expansion

Established operating locations in China, Hong Kong, Japan, South Korea, and the United States, and established strategic partnerships in Europe.

The world's first long-acting alpha-interferon drug approved for the treatment of PV

Successfully developed a new generation of long-action pegylated interferon with our in-house developed "PEGylation technology platform," addressing the inadequacies of current medication to treat PV for physicians and patients.



1-1

A fully integrated innovative biopharmaceutical company

About PharmaEssentia

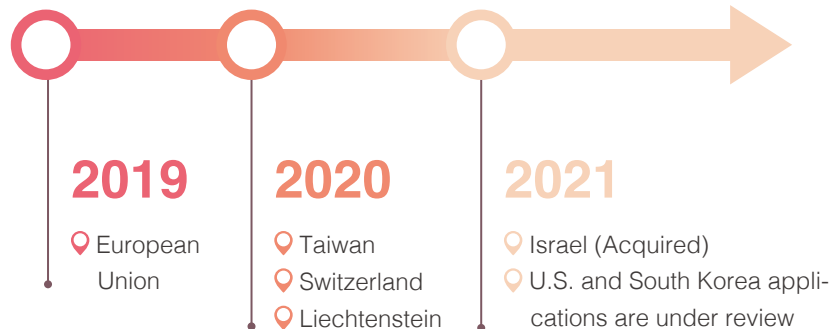
GRI 102-1~7

PharmaEssentia is based in Taiwan. In addition to the manufacturing and production capabilities and the cultivation of talents in the field of local biotechnology and new drugs, we also actively expand the global market and develop strategic alliance partners. We commit to becoming the top-tier innovative biopharmaceutical company and the forerunner in the field of MPN.

The Company has developed highly site specific PEGylation technology or “PEGylation coupling reaction technology platform” and small molecule synthetic drug technology. It is superior to competitors in terms of side effects and maximum patient tolerance (MTD). The Company’ has self-developed innovative biologic drug “Ropeginterferon alfa-2b (P1101),” the strategic partner AOP Orphan not only has successively obtained marketing approval in many countries in Europe and is deployed under the brand name BESREMi®, but it has also received Israel’s approval in early 2021. The marketing authorization is the first approval obtained by BESREMi® in West Asian countries. Soon, it is expected to receive further permission from the South Korean and U.S. authorities to treat PV and gradually expand the sales of Ropeginterferon alfa-2b (P1101) in the global market.

	Mission and vision	<ul style="list-style-type: none"> • Become the top-tier innovative protein biopharmaceutical company • Established the first fully integrated protein innovation biopharmaceutical company in Taiwan, combining R&D, clinical trials, manufacturing and sales stages of new drugs.
	Operating locations	With PharmaEssentia Corporation in Taiwan as headquarters, global operating locations include the United States, China, Japan, South Korea and Hong Kong.
	Total number of employees at the end of 2020	217 in Taiwan; 277 in total worldwide
	Consolidated revenue and equity at the end of 2020	Net operating revenues of NT\$557 million; equity of NT\$3.92 billion

Overview of obtaining Ropeginterferon alfa-2b (P1101) marketing authorization approval in the global market



Ropeginterferon alfa-2b (P1101) BESREMi® is approved to treat adult patients with PV without symptomatic splenomegaly in nearly 20 countries, including the European Union, Taiwan, Switzerland, Liechtenstein, and Israel. The indication is a type of MPN, and patients of severe cases may develop life-threatening acute myeloid leukemia (AML).

Partnerships along the value chain

One of the Company's' philosophies is to give back to society by creating value in Taiwan's biotechnology industry chain based on its original intention. PharmaEssentia has corresponding strategic partners and individual cooperation models at different stages of the industry chain based on professional and cost considerations. We cooperate with every partner in the upstream, midstream, and downstream of the industry chain with the cooperative spirit of " Mutual benefit, Mutual prosperity ." We look forward to leveraging each other's strengths to maximize synergies and work toward shared sustainability values.

2020	R&D of new drugs	Pre-clinical Trial	Clinical Trial	Manufacturing and production	Registration	Marketing and sales
R&D Cooperative Entity	Academic research institutions (e.g., Academia Sinica, domestic and overseas universities).	<ul style="list-style-type: none"> Contract Research Organization (CRO) Authorized collaborating international biopharmaceutical companies, Research foundations. 	<ul style="list-style-type: none"> Clinical trial hospitals CROs European strategic partner AOP Orphan 	<ul style="list-style-type: none"> Supplier/Contractor Contract Manufacturing Organization (CMO) 	Authorizing cooperation with International biopharmaceutical companies or CROs	Authorizing strategic sales partners or Entrusted marketing channel
Cooperation model	We are cooperating with universities around the world to develop a potential drug jointly.	<ul style="list-style-type: none"> We are cooperating with professionally qualified CROs with multiple international certifications. We actively interact with local research foundations, patient rights groups, and hospitals in various countries to understand disease needs and trends. We are contracting clinical trials to international biopharmaceutical companies. 	To ensure that both parties agree on products and quality requirements, the Company requires suppliers to sign a "Quality Agreement," which specifies the Company's rights and responsibilities for quality and technology-related topics. Furthermore, we cooperate with CMOs who is professional and qualified with international certifications.	Authorizing international biopharmaceutical companies or CROs to conduct clinical trials and drug license applications.	Strategic alliances with foreign partners or entrusted marketing channels familiar with the local market to jointly expand the local sales market.	
Results	For the development of potential drugs for specific cancers through industrial-academic collaboration with domestic universities, please refer to chapter 6, section 6.2.	Ropeginterferon alfa-2b (P1101) completed phase III clinical trial for hepatitis C (HCV) and initiated enrollment of subjects in phase III clinical trial for ET.	Thirty-two new suppliers were verified in 2020 and became available to the Company as a list of qualified suppliers. Nine of them were required to sign quality agreements following our standard operating procedures, and all of them had signed in 2020.	Licensing partner Athenex's Tirbanibulin ointment (product code KX 01), brand name Klisyri [®] , was approved by the FDA in December 2020 for the topical treatment of Actinic Keratosis (AK) on the face or scalp. Tirbanibulin ointment had been added to the authorized areas and indications. Please refer to chapter 6, section 6.3.	BESREM [®] is marketed in Europe, the Middle East, and the Independent States Association by an authorized European partner, AOP Orphan. It has been approved for marketing in nearly 20 countries, including the European Union, Switzerland, Liechtenstein, and Israel.	

1-2

Two major globalization strategies

Globalization strategies

GRI 102-14

PharmaEssentia has formulated two major globalization strategies. Carry out global systems and improve drug and market development efficiency through “establishing foreign subsidiaries” and “partnering in-licensing, out-licensing and development “ Our product management approach is to leverage our scientific research, development capabilities, and technology platform to address unmet patient needs. Our market management approach provides patients with adequate access to medicines, stabilizes supply sources, and sets fair and affordable drug prices. In terms of corporate governance, we are committed to gradually integrating ESG topics such as environmental, social, and governance topics with corporate development decisions, management processes, and corporate culture, and continuously optimizing the Company’s operating model and implementing various operational management policies to become a high-performing, trusted and respected international innovative biopharmaceutical company. As of the end of 2020, our product Roppeginterferon alfa-2b (P1101) is in clinical trials or drug submission for various indications worldwide, enabling us to promote the use of each product indication for the benefit of patients around the world.

Our three primary strategic pillars



Strategic pillar 1

Maximize the value of technology platforms and products to increase profits

- We are building Roppeginterferon alfa-2b into a leading brand for MPN, hematologic, and oncologic diseases and increasing patients’ loyalty to medication.
- Using PEGylation as a technology platform as well as the intellectual property and R&D capacity accumulated by successfully developed Roppeginterferon alfa-2b (P1101) as a product, to continue developing other innovative products for therapeutic trials of indications, such as ET, hepatitis, and immunotherapy for cancer treatment to shorten the development timeline of new products and reduce R&D risks and research funding.



Strategic pillar 2

Recruit outstanding talents and sound operation management

- Combine the layout strategies of subsidiaries worldwide, recruit local high-level talents from subsidiaries, shorten international differentiation, and accelerate market entry.
- We are improving the comprehensiveness of local service offices of our subsidiaries in the world and reducing overall costs through efficient operation and management models to benefit patients better.



Strategic pillar 3

Continuous innovation and development to create long-term company value

- Developing or introducing potential new drug with strategic alliance partners through licensed cooperation or permits expand the Company’s diverse pipeline.
- Sustainable development, risk management, and other functional groups have been established to plan, promote, execute, follow-up, and respond to related sustainable management topics, optimize corporate governance, and respond to stakeholders’ expectations.

PharmaEssentia's Global Territorial Expansion



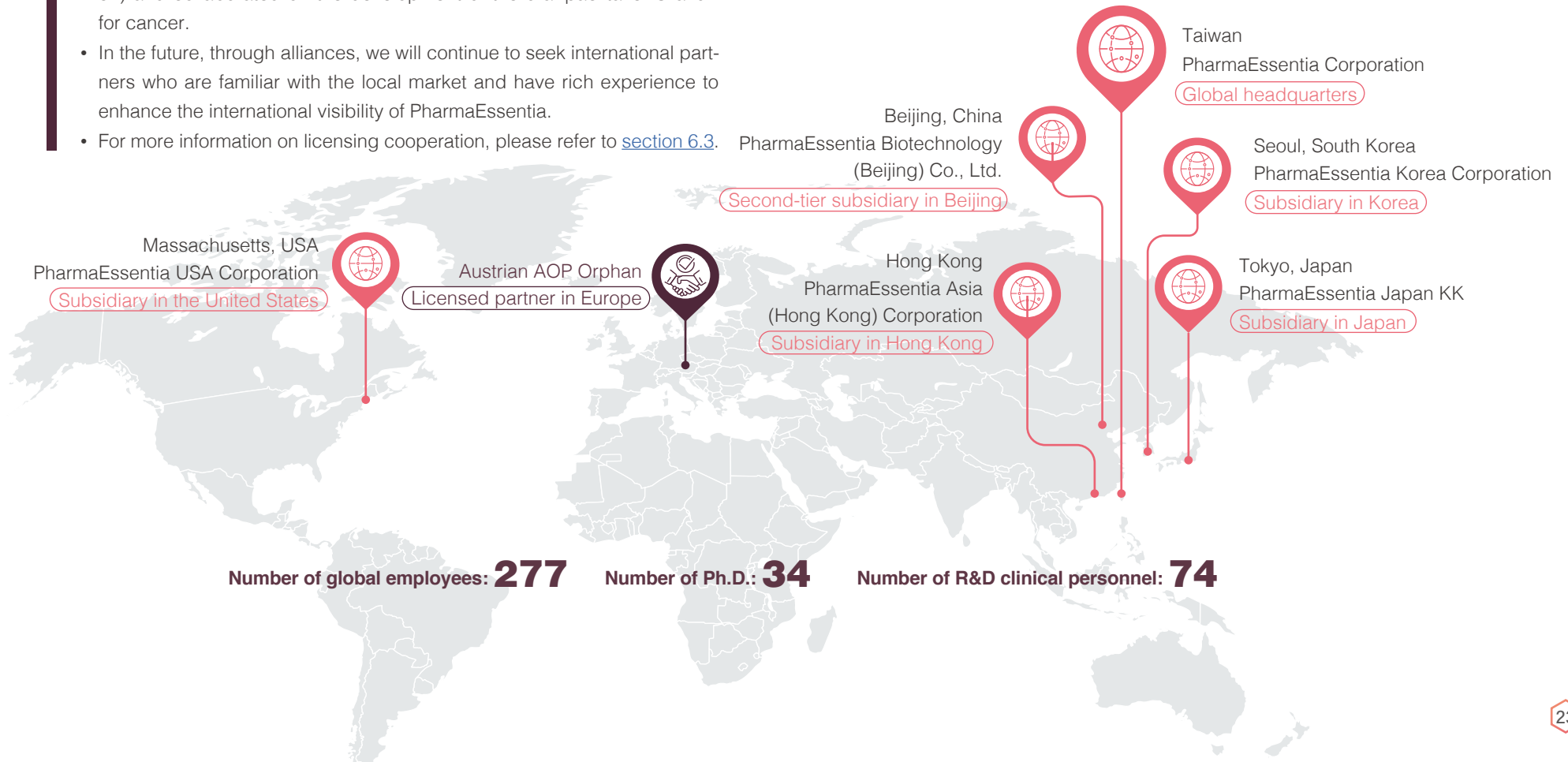
Partnering in-licensing, out-licensing and development

- Licensed the development and sales of Ropeginterferon alfa-2b (P1101) in Europe, Middle East, and Commonwealth of Independent States to our partner, AOP Orphan.
- Authorized the introduction of Athenex's Tirbanibulin ointment (code KX 01) and collaborated on the development of the oral paclitaxel Oraxol[®] for cancer.
- In the future, through alliances, we will continue to seek international partners who are familiar with the local market and have rich experience to enhance the international visibility of PharmaEssentia.
- For more information on licensing cooperation, please refer to [section 6.3](#).



Establishing foreign subsidiaries

- Established operating locations in the United States, China, Japan, South Korea and Hong Kong.
- Hired local scientists and high-level management talents to communicate with local authorities on issues regarding clinical drug permit applications and marketing strategies.



1-3

R&D of innovative biopharmaceuticals

Materiality Topic

Management approach on innovative drugs research and discovery

The R&D process of a new drug begins with drug discovery, innovative research, evaluation of the drug mechanism, and validation of the value of the new drug before moving on to animal testing and human clinical trials. After confirming that the new drug has clinical efficacy, it can be inspected, registered, and marketed. Overall, it takes an average of 10-15 years for the R&D of new drugs and massive investment in research funds to develop a solution for the treatment of human diseases so that patients can obtain safe, effective, and high-quality medicines. In our management strategy for the development of new biologic drugs and expanding the application of the new generation of long-acting interferon Ropeginterferon alfa-2b (P1101) to the field of MPN, the Company also conducts various exploratory research. It includes the monoclonal antibodies for the development of immune checkpoint inhibitor PD-1, combined with Ropeginterferon alfa-2b (P1101) to enhance the patient's immune response against various cancers. In 2020, we invested a total of nearly NT\$922 million in R&D expenditures, an increase of approximately 44% compared to 2019. We will continue to invest more than NT\$ 1 billion in R&D in 2021. This shows that we spare no effort to invest in R&D resources compared to our domestic counterparts. We always commit to creating the highest quality new drugs with the best technology and quality control to enhance our research and development capabilities.

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GRI 103-3



Policies

From the early stage of basic research, product technology research, and preclinical trials, to the middle stage of trial production, phase I and phase II human clinical trials, to the mature phase of product trials and phase III human clinical trials, the Company follows the internal control R&D cycle rules, intellectual property patent application protection and related regulations to seek new products with new technologies that are competitive in the market, and to explore the use of its technology to develop new drugs that have not yet been met. The aim is to seek new products with competitive technologies and to explore unmet needs for new drugs using our technologies. PharmaEssentia complies with the "Declaration of Helsinki," "International Council for Harmonisation of Technical Requirements - Good Clinical Practice (ICH-GCP)," GXP, and other international standards as management policies.



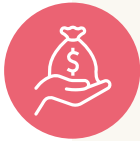
Commitments

Focusing on four key disease areas, we innovate new biologic drugs with the best technology and highest quality and contribute to improving the health of every humankind by providing innovative and reliable medicines



Responsibilities

- The new drug R&D division mainly coordinates new drug discovery. The decision-maker for new drug research is the "Project Evaluation Team," which includes interdepartmental representatives and internal senior management executives. The resolutions discussed in the "Project Review Meeting" are jointly decided to establish an R&D project. The project leader will coordinate the progress of the project and complete the report regularly, while the clinical operation department manages the clinical trial section
- Sustainable Development Execution Center - Access to Medicine Team



Resources invested

The resources invested in the research and discovery management of new drugs will be allocated based on the importance of the project and the premise of “unmet medical need.” The human resources and material resources invested will have different plans depending on the project. 74 R&D clinicians worldwide invested in 2020, with total R&D spending of NT\$ 922 million.



Goals and targets

2021 Short-term Goals

1. Expand the clinical application of Ropeginterferon alfa-2b (P1101) to areas of MPN other than PV, such as ET and viral hepatitis disease (HBV/HDV).
 - Phase III clinical trial of Ropeginterferon alfa-2b (P1101) in ET in China, Hong Kong, South Korea, USA, Singapore, and Europe.
 - Initiate a phase I clinical trial of HBV/HDV in Taiwan.
2. Sponsor Ropeginterferon alfa-2b (P1101) drug and a portion of the cost to support the Chronic Myeloid Leukemia (CML) Investigator-Initiated Trial (IIT) for the benefit of patients in South Korea.
3. License development of KX 01 entered clinical trials in Japan in phase I/II.
4. Promote Ropeginterferon alfa-2b (P1101) for Adult T-cell Leukemia/Lymphoma (ATL) IIT in Japan.
5. Actively develop therapeutic antibodies (PD1) and antiviral drugs (HBV), continue to develop a vaccine and initiate a clinical development program for a new vaccine.

2022~2024 Mid-term Goals

1. Actively conduct clinical trials for cancer immunotherapy drugs (TCRT), enter Good Tissue Practice (GTP) production and prepare to apply for the Investigational New Drug (IND).
2. Actively introduce cell therapy-related technology cooperation projects, construct cell factories using imported technology, and continuously evaluate the direction of new drug development to apply for a cell therapy product clinical trial.
3. Develop innovative process technology platforms to enhance production efficiency, reduce costs, shorten development time, apply new process technology platforms to new drug products, and apply for a clinical trial.
4. Actively implement PEGylation program for new target proteins and applied for an IND.
5. Actively evaluate products related to immune targets and select one product for development.
6. Continue to promote international Ropeginterferon alfa-2b (P1101) ET phase III clinical trial and drug license submission.

2025 Long-term Goals

1. Continue to seek licensing or permission to develop or introduce new drug candidates with strategic alliance partners, and actively pursue various medical urgency drug development project themes to expand the Company's product line.
2. Speed up the progress of vital clinical trials and submit for various drug licenses in each country to maximize product benefits.



Evaluation of management approach

Evaluation of Management mechanisms

- All R&D projects follow the internal R&D operation cycle and are managed quarterly according to the financial information compiled by the finance department for project progress and execution efficiency and are evaluated every six months for project cost control. The “project team” members will regularly make decisions on whether to continue the project when there are significant R&D results or milestones set out in the proposal.
- Large-scale projects and annual project budgets must be submitted to the Board of Directors for approval before R&D can be conducted.
- R&D department monthly review according to each R&D project for schedule management.
- The finance department regularly tracks the financial management of R&D projects following the actual and estimated expenditures of each R&D project every quarter and reports to the Board of Directors quarterly to explain the divergence analysis.
- The audit unit performs audit operations of the R&D cycle management mechanism under the annual audit plan each year.
- The clinical department reviews the Company’s clinical trial progress quarterly.

2020 Evaluation Results

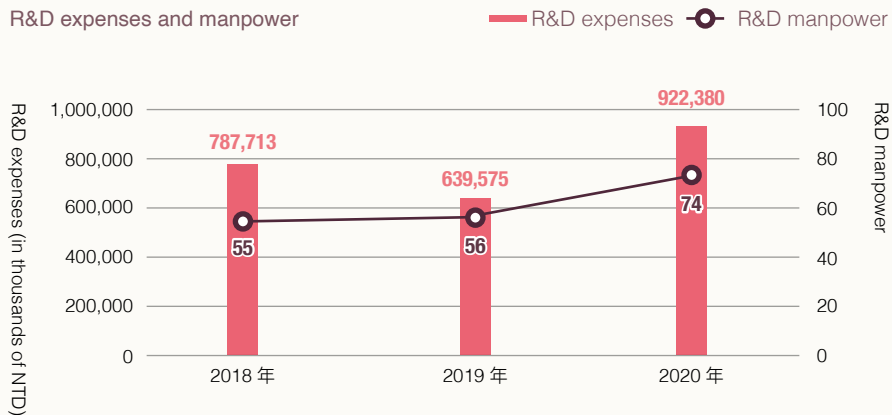
- The project team regularly evaluated and made decisions on various projects in R&D, and the overall average control evaluation was reasonable.
- We are authorized to introduce KX 01 for helio keratosis, which is expected to apply for marketing authorization from TFDA in Taiwan in 2021.
- Ropeginterferon alfa-2b (P1101) underwent clinical trials in different stages in many countries for diseases related to Essential Thrombocythemia (ET), viral infection diseases, and neoplastic diseases.

New drug discovery and innovative research

PharamaEssentia is a protein-based biopharmaceutical R&D company with a PEGylation technology platform as the most significant competitive advantage to improve patient tolerance and convenience significantly. Applying the Company’s self-developed PEGylation technology platform to different indications can shorten the development timeline of new products, reduce the risk of new product R&D and research funding, and create an

advantageous product portfolio for future business expansion. It can reduce the possible competition risk of a single product. Our exploratory research trials focus on our four major disease areas: Hematology, Oncology, Infectious Diseases, and Dermatology. For more information on the Company’s core function of R&D on new drugs for proximate social impact, please refer to [chapter 6, section 6.2](#).

Growing R&D expenditure



Note: 2020 R&D expenses were consolidated financial data; R&D human resources data included the number of global R&D clinical units.

4 main R&D product

- Ropeginterferon alfa-2b (P1101)
- Kinase inhibitor RAYKLIRA™ (Code KX01)
- Ropeginterferon alfa-2b (P1101) + immune-checkpoint inhibitors Anti-PD-1 antibody
- Oraxol®

New drug competitive advantages

Ropeginterferon alfa-2b (P1101) New generation of long-acting PEG interferon

- High tolerance
- Stable and single component
- Used for multiple indications
- Low side-effects
- High purity
- Reduce dosing frequency to once biweekly

4 main disease focuses

- Hematology
- Oncology
- Infectious Diseases
- Dermatology

Pursue animal benefit in preclinical animal experiments

To ensure that the relevant IACUC regulations conduct animal experiments, we require researchers to minimize the use of experimental animals as much as possible. In terms of preclinical animal experiments, we screen domestic and foreign CROs, all of which must be GLP-certified professional CROs. Some of the CROs have an animal welfare protection committee that humanely conducts animal experiments. We also conducted site

visits to examine the process of managing animal trials in the CRO operation to ensure that the new drug under study would pass the animal trial stage and move on to the next phase of human endeavors. For more information on our ethical and moral approach to managing preclinical animal studies, please refer to [chapter 2, section 2.2](#).

The rigorous human clinical trial process

SASB HC-BP-210a.1

Science, ethics, and business are all critical elements influencing the clinical trials of new drugs and require the most stringent oversight and accountability standards by local food and drug regulatory authorities. PharmaEssentia has completed 14 internal standard operating procedures for clinical operations to maintain the quality of human clinical trials, with another 11 under development. We have an audit and inspection mechanism in each clinical development phase and comply with the "Declaration of Helsinki," "International Council for Harmonisation of Technical Requirements - Good Clinical Practice (ICH-GCP)," and perform phase I, II, III clinical trials following the approved trial plan and relevant local laws. During the clinical trial process, the principal investigator (PI) of the test will regularly perform a health assessment on return visit subjects and monitor and report any adverse events. All adverse events will be treated or dealt with appropriately. Appropriate follow-up periods are also set after the clinical trial process to ensure the safety of subjects.

Clinical Trial Process



Before each phase of clinical trial:

- Investigational new drug (IND) application and related documents shall be reviewed and approved by the competent authorities and the Institutional Review Board (IRB).
- Convening principal investigator (PI) meetings for relevant trainings.
- Written informed consent (ICF) shall be obtained from the subjects, and screening of suitable subjects shall be strictly conducted according to the inclusion and exclusion criteria of the investigational new drug (IND) application.

After each phase of clinical trial:

- A summary of clinical trial healing efficacy and safety data shall be presented.
- On-site inspections, and benefit and risk assessments shall be granted in a written review format by the competent authorities before conducting drug marketing.

Launching international clinical trials to enhance the competitiveness of drugs

Launched international phase III clinical trial for the treatment of ET.

Ropeginterferon alfa-2b (P1101) clinical trial has reached 800 patients

Ropeginterferon alfa-2b (P1101) has been used in clinical trials related to ET, hepatitis virus infection diseases, and neoplastic diseases and has also undergone clinical trials in different stages in many countries. ET has also started phase III clinical trials in Taiwan, Japan, South Korea, China, and the United States. The competent authorities have approved the clinical trial plans in various countries of participating countries. This trial enrolled 160 subjects and is scheduled to complete a phase III clinical trial in 2022, upon completion. It is anticipated that Ropeginterferon alfa-2b (P1101) will be licensed to treat ET in each participating country. As of

the end of 2020, the company conducted clinical trials with Ropeginterferon alfa-2b (P1101) in Europe, Taiwan, Japan, South Korea, China, and the United States, reaching a cumulative total of 800 patients worldwide (including IIT but excluding healthy subjects). In the future, we will continue to meet new challenges, create innovative medicines that will benefit the health of people worldwide, and enable PharamaEssentia to make a name for us in the global pharmaceutical manufacturing arena. For more information on the Company's use of new drugs in trials to treat MPN-related diseases, please refer to [chapter 6, section 6.2](#).



Internationally recognized manufacturing and production

Ropeginterferon alfa-2b (P1101) production certification blueprint

As the development process before the launch of a new drug is time-consuming and requires considerable amounts of capital investment, and the risks are high. The formation of a full-scale industrial chain takes an extended period. Therefore, domestic new drug companies barely invest in the construction of protein pharmaceutical factories, considering the factors such as technology, capital needs, talents, and industrial resource integration capabilities. To achieve our goal of being a fully integrated pharmaceutical company, we have established a complete vertically integrated supply chain from total production, quality control, filling, and shipping to global markets, becoming a leading international pharmaceutical company.



Fig 3: PharmaEssentia's Taichung biopharmaceutical plant is the first EMA-inspected and GMP-validated protein pharmaceutical plant in Taiwan.

2012

Completed construction of a biopharmaceutical manufacturing plant in Taichung.

2013

Taichung biopharmaceutical manufacturing plant obtained GMP certification.

2018

First protein pharmaceutical factory in Taiwan passed the inspection from EMA and obtained certificate for protein drug factory from GMP.

2020

The newly established filling plant received GMP and Good Distribution Practice (GDP) certification from the Taiwan TFDA.

2021

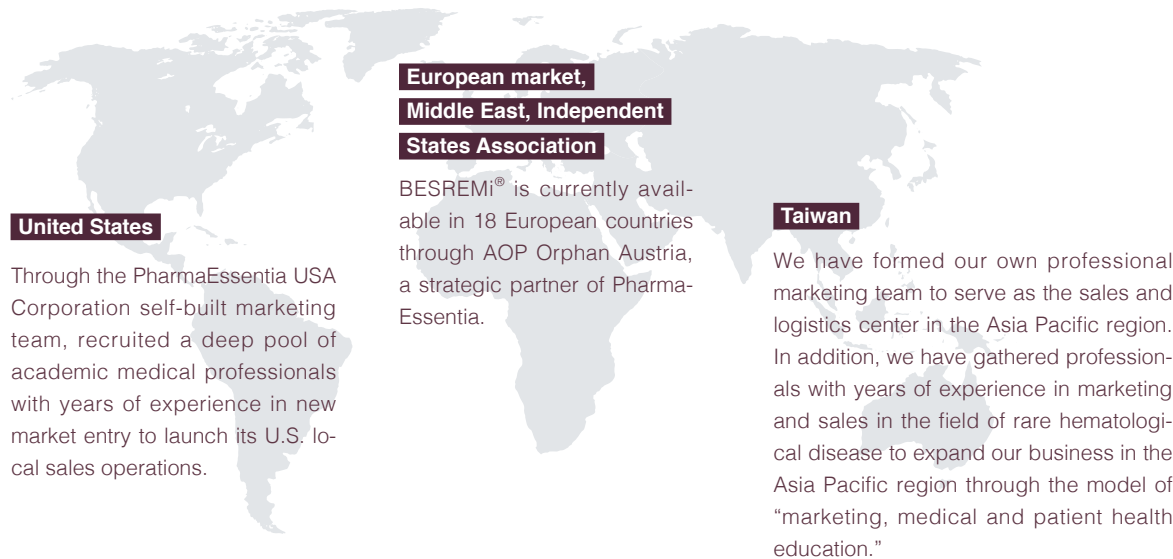
The GMP inspection result by South Korea MFDS was acceptable, and is expected to obtain South Korean marketing authorization approval in the 2nd quarter of this year.

Completed the blueprint for the full certification required for the production of Ropeginterferon alfa-2b (P1101) by PharmaEssentia.

1-5

Global commercialization blueprint

Deployment of a local team of experienced professionals



After years of R&D and clinical trials, Ropeginterferon alfa-2b (P1101) is used for the treatment of PV and has been approved for marketing in nearly 20 countries, including Europe, Taiwan, Switzerland, Liechtenstein, and Israel under the trade name BESREMI®/ 百斯瑞明® as of the date of this report. In South Korea, we obtained a GMP inspection in early 2021 and expect to receive the drug certificate soon. To serve patients in the local market

with the best execution and effectively comply with each country's market regulations while marketing our pharmaceutical products, we have authorized our partner, AOP, to be in charge of the European, Middle East, and Independent States Association markets. We have set up subsidiaries in the Asia Pacific and the United States with experienced professional teams to promote local sales.

European market

SASB HC-BP-240a.1

SASB HC-BP-000.A

Used by nearly 1,000 patients in 18 countries

As of the first quarter of 2021, BESREMI® has been used by nearly 1,000 patients in 18 European countries



Fig4: BESREMI® sold in Europe.

In 2019, Ropeginterferon alfa-2b (P1101) was first marketed in the EU under the brand name BESREMI®. Through our strategic partner AOP Orphan Austria, who is familiar with European local market regulations and has many years of experience in marketing new drugs, BESREMI® is now available in 18 European countries and is used by approximately 1,000 patients. Looking ahead, we expect our sales revenue and patient utilization to continue to grow in 2021, and we hope to recover the costs we have invested in the development of new drugs year by year, which will be returned to our shareholders and investors.

Taiwan and Asia-Pacific markets

Sales and distribution in Asia-Pacific

Based in Taiwan as headquarters, self-build professional team to expand the sales and distribution in the Asia-Pacific region patients in 18 European countries



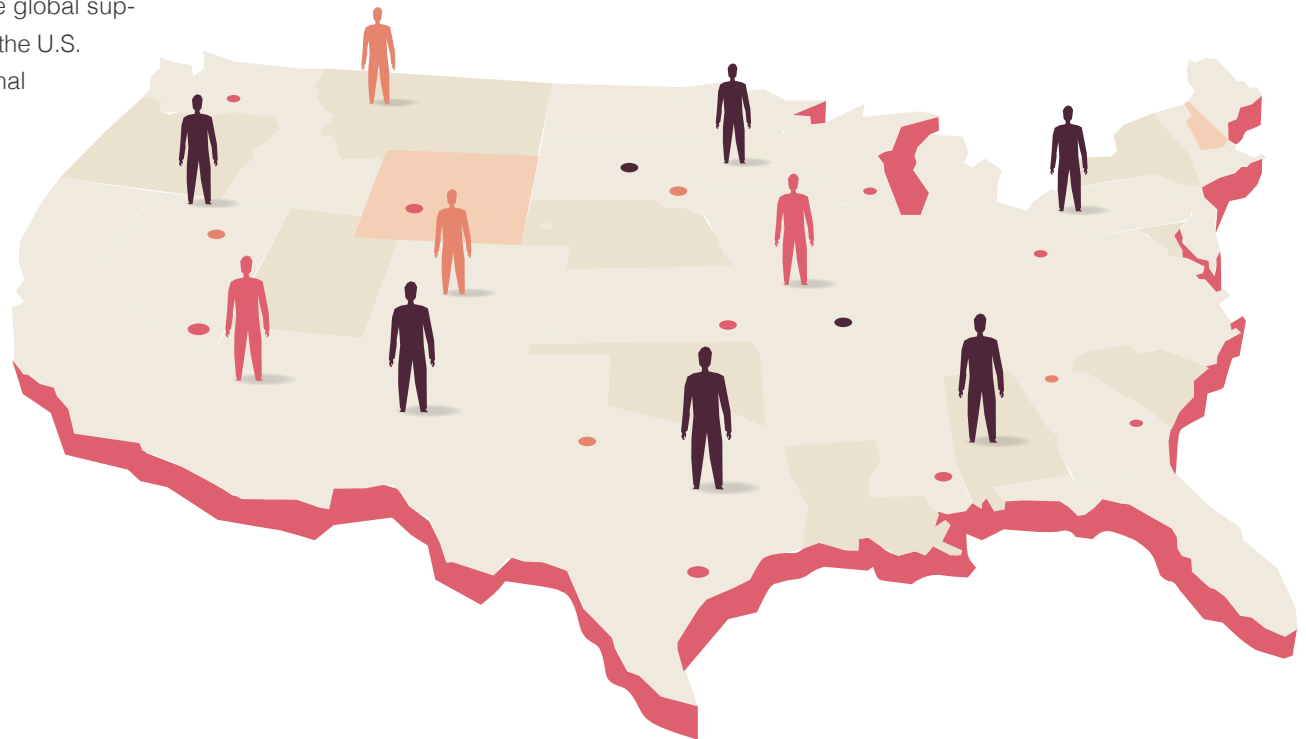
Fig5: 百斯瑞明® sold in Taiwan.

For the Taiwan market, since Taiwan's regulations and systems in terms of drug license submission, medical regulations, and universal health insurance are entirely in line with the top 10 advanced countries in the world, in the process of Ropeginterferon alfa-2b (P1101) obtaining drug certificates from all over the world, Taiwan is the first country to use the results of clinical trials applying for EMA marketing authorization approval and obtain the approval of the competent authority to waive connection trials and directly obtain drug licenses. In May 2020, Ropeginterferon alfa-2b (P1101) had obtained Taiwan's drug license for PV by TFDA, and it is expected to be marketed at National Health Insurance price (NHI price) in Q1 of 2021. Our marketing strategy for Taiwan and the entire Asia-Pacific region, with our own professional team as the sales center, is described below, with the aim of increasing the visibility and sales of our drugs in the market and providing better clinical outcomes for our patients.

Marketing Strategy	2020 Implementation and Performance
On the premise of compliance with marketing ethics, actively communicate with clinicians to improve clinicians' understanding of the treatment of PV and their familiarity with 百斯瑞明®.	Participated in 3 seminars with a total of 240 participants in 2020 to discuss the current status and difficulties of the treatment of diseases and drugs in Taiwan, as well as clinical experience sharing, so as to enhance the Company and marketing drug awareness.
Strengthen health education support for patients so that patients can better understand the long-term effects of 百斯瑞明® and the benefits of disease control.	Set up a health education platform, "MPNi Care," to build up courage for patients by integrating resources and uniting patients. For more information about the Company's actions and achievements of patient care and education, please refer to chapter 6, section 6.4
Through sponsoring the MPN Asia and other annual conferences related to the Company's intertwined disease fields, communicate with doctors, experts and scholars worldwide.	<ul style="list-style-type: none"> Sponsored the 2020 American Society of Hematology (ASH) to announce the potential of Ropeginterferon alfa-2b (P1101) for treating patients with PV. For more information about the Company's results published at the ASH, please refer to chapter 6, section 6.2. Continue to sponsor the holding of the 2021 MPN Asia, and to respond to the epidemic and avoid large-scale gatherings, online video conferences will be held. For more information on sponsoring MPN Asia, please refer to chapter 6, section 6.5.

United States Market

The PharmaEssentia USA Corporation (hereinafter referred to as U.S. subsidiary) has a complete high-level management team in place, recruiting an average of 10 years of experience in hematology-oncology professionals to form a strong marketing team and an average of nearly 30 years of experience in the market. The admission team has the professional ability and knowledge in the launch of oncology and drug insurance negotiations to fully promote the commercialization of Ropeginterferon alfa-2b (P1101). We have obtained marketing authorization in 23 states in the U.S., with only three states remaining approved. Another 16 states do not require a special marketing authorization, and 6 states' authorization will automatically take effect upon FDA approval. The Company has a stable and safe global supply chain in place and is ready to meet the demand for drugs in the U.S. market in the coming year, and has deployed local professional drug distributors and comprehensive patient assistance services to ensure that drugs can be marketed and sold after obtaining marketing authorization approval, thus realizing the sustainable spirit of accessing to medicine.



Chapter 2

Business Ethics, Integrity and Compliance

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Chapter 2

Business Ethics, Integrity and Compliance



Summary of Chapter 2

Highlights of 2020

Sound corporate governance is the foundation of business operations and the primary key to attracting long-term and continuous investment. In 2020, internal audit department completed 44 audit actions and reported 100% of deficiency improvements. Since 2019, we have drawn up a 5-year sustainable governance development plan, committed to promoting management strategies and action guidelines for various sustainability topics, and striding forward with the core vision of realizing the company's sustainable value and deepening the Company's deepening sustainable governance culture. In order to ensure that this goal is carried out correctly and efficiently, the Executive Center for Corporate Sustainability (ECCS) of PharmaEssentia has been formally established. There are 5 taskforces responsible for the communication, performance results, and goal setting on sustainability topics in different aspects of ESG to strengthen the communication with stakeholders and create a good channel for interaction. To assist corporate governance, the ECCS introduced COSO's "Enterprise Risk Management Framework" in 2020 to help the Company consider more and more aspects of risk and the importance of its management in the process of setting strategy and driving performance, as a means of identifying ESG-related non-financial risk topics and strengthening ESG risk management and communication with internal and external stakeholders.

Relevant material topics



Relevant stakeholders



Performance highlights

Voluntary release of the first issue

Voluntary release of the first 2019 Sustainability Report in English and Chinese in 2020.

78 countries with a total of 74 cases

Valid patents

Included in domestic and foreign index stocks

For example, MSCI Taiwan, TPEX 200 Index, and TIP Taiwan Bio Index.

Introduced ESG risk management framework for the first time

Use COSO "Enterprise Risk Management Framework" to complete the Company's internal ESG related non-financial risk training and identification.

First established Sustainable Development Organization

Executive Center for Corporate Sustainability of PharmaEssentia reports to the Board of Directors quarterly on the progress of sustainability goals implementation.

29 countries with a total of 71 cases

Valid trademarks

100% Attendance rate

Functional committees

Ranking rosed to TOP 2

Range of 2020 Corporate Governance Evaluation Results

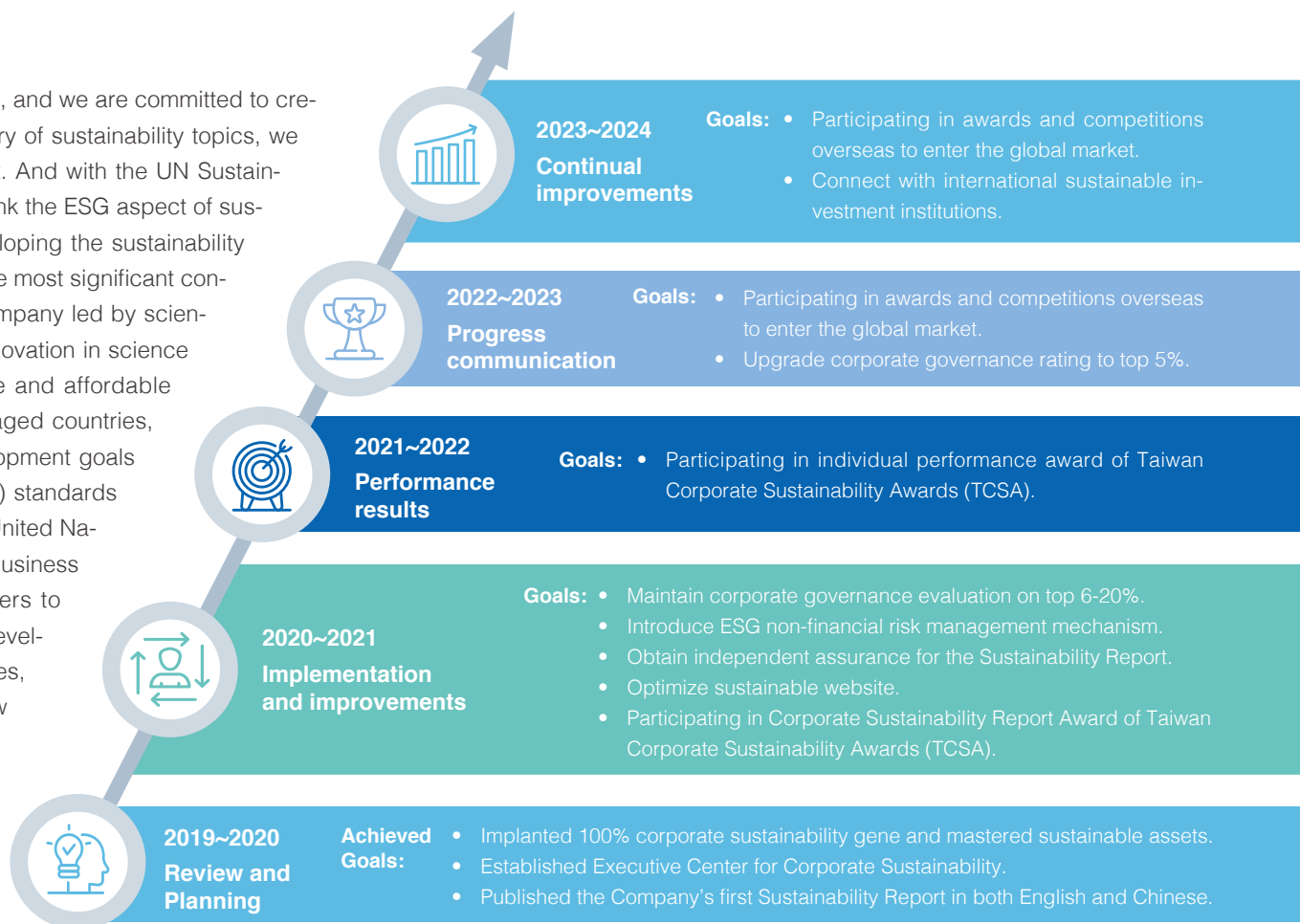


2-1

ESG governance

The 5-year strategy for sustainable development of PharmaEssentia

2019 was the first year of promoting sustainability by PharmaEssentia, and we are committed to creating long-term shared value with stakeholders. Through the inventory of sustainability topics, we formulated a 5-year sustainable development strategy and blueprint. And with the UN Sustainable Development Goal (SDG) 3: health and well-being as the core link the ESG aspect of sustainable development. We believe that "health" is the basis for developing the sustainability topics of PharmaEssentia's ESG, and it is also where we can make the most significant contribution to the world. Therefore, as a biotechnology and medical company led by scientific research, we solve unmet disease needs through continuous innovation in science and technology, and make the prices of our medicines reasonable and affordable for patients, and increase the availability of economically disadvantaged countries, supporting SDGs from the core competency. Our sustainable development goals also integrated the Sustainability Accounting Standard Board (SASB) standards for the biotechnology pharmaceuticals industry, GRI standards, the United Nations Global Covenant, and the Access to Medicine Index with our business operation and strategy. In addition to allowing external stakeholders to recognize PharmaEssentia's determination to promote sustainable development, we also enable internal stakeholders, especially all colleagues, to have a consistent goal and code of conduct. While developing new drugs, we also promote the economy's ecological balance and sustainable development, society, and the environment. The Company strives to fulfill the founding purpose: "Better science, Better lives." In 2020, the first 2019 Chinese and English Sustainability Report of PharmaEssentia was published, revealing the specific performance of ESG's sustainable operation.



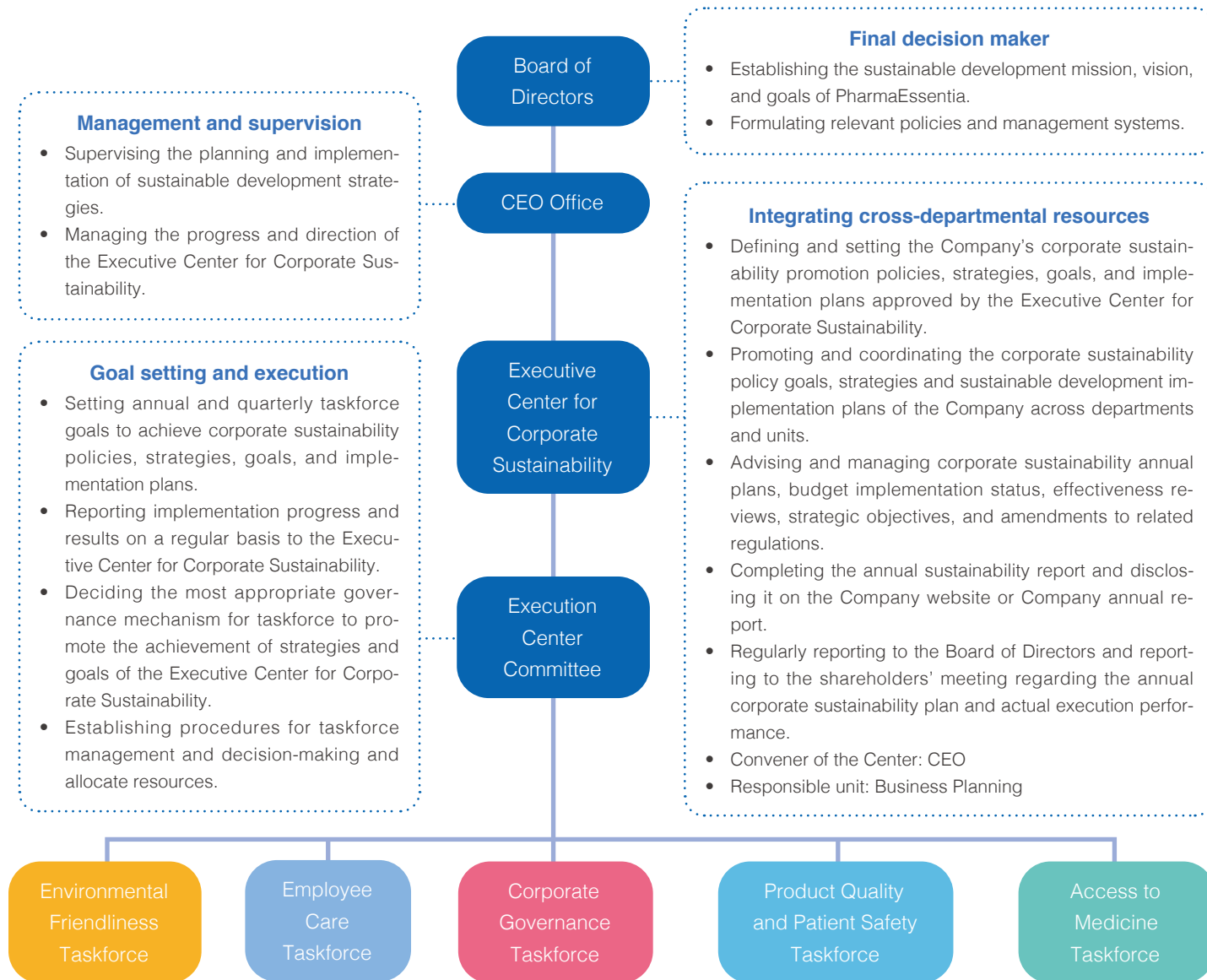
Sustainability management

GRI 102-19 GRI 102-20

The Execution Center for Corporate Sustainability of PharmaEssentia was established under the CEO, with 5 cross-departmental functional taskforces, including the Environmental Friendliness Taskforce, the Employee Care Taskforce, the Corporate Governance Taskforce, the Product Quality and Patient Safety Taskforce, and the Access to the Medicine Taskforce, to manage 14 highly significant topics of the Company. The Execution Center for Corporate Sustainability is responsible for planning and promoting cross-departmental and unit-related sustainable development policies, goals, strategies, and sustainable development implementation plans and will report the project's progress to the Board of Directors quarterly.



GRI 102-31~33





Take the United Nations Sustainable Development Goals 3 as the core.

Address unmet disease needs through PharmaEssentia's science and innovation to deliver access to medicines for patients worldwide.

The ESG aspects and the SDGs to which the 5 taskforces corresponding to

E

Ensure the health of PharmaEssentia's employees and the residents around the plant through actions to reduce chemical, air, water, soil and other pollution.



We examine the management of waste and toxic chemicals from a life-cycle perspective to prevent environmental pollution from harming human health.



We are committed to reducing energy consumption intensity through a number of energy efficiency initiatives. We are progressively using the Task Force on Climate-related Financial Disclosures (TCFD) as a framework for disclosing climate change risks and opportunities to implement climate action.



Environmental Friendliness Taskforce

- ★ Waste management
- ★ Toxic chemical substance management

S



Prepare for possible future public health emergencies, we continue to promote and collaborate on the development of vaccine candidates.



We regularly report on the proportion of women on boards and in management-level roles, and support the career development of women managers to promote a gender-balanced and inclusive workplace.



In order to ensure that our colleagues interact with healthcare professionals in a reasonable manner and in accordance with relevant drug and medical regulations, we comply with WHO and national ethical standards for pharmaceutical marketing. In 2020, we established three major supplier management priorities to ensure a stable procurement supply with our supply partners.



To support the health and well-being of our employees, we provide them with quality compensation and benefits, and ensure that they have appropriate career development plans through comprehensive education and training, regular performance appraisals, and the promotion of employment and overall economic growth.



Our greatest impact on health is the successful development of innovative products. Through our science and innovation, we develop differentiated, high quality medicines to improve the health of patients worldwide.



We have built diverse partnerships among academia, strategic alliances, and intellectual property sharing companies to pursue breakthrough innovations in support of global goal SDG 3.

Employee Care Taskforce

- ★ Occupational health and safety
- ★ Talent cultivation and Career development

Product Quality and Patient Safety Taskforce

- ★ Patient safety
- ★ Product quality and safety management
- ★ Stable and secure supply chain

Access to Medicine Taskforce

- ★ Access to medicine
- ★ Innovative drugs research and discovery

G

Realize our business opportunities while providing patients with reasonable, affordable, correct and easy access to the medicine they need, through an approach to proximate drug governance that is closely aligned with our business development strategy from our core competency.



We are committed to upholding the spirit and fundamental principles of human rights protection as set forth in the "United Nations Global Compact," the "United Nations Universal Declaration of Human Rights" and the "ILO Declaration on Fundamental Principles and Rights at Work." We have a zero-tolerance approach to bribery and any form of corruption and have developed an anti-bribery and anti-corruption action plan.



We believe that a multi-faceted partnership between corporations, governments and NGOs that effectively harnesses each party's unique expertise will help develop and deliver the medicines in a timely manner to people around the world to meet the healthy lives.


















Corporate Governance Taskforce

- ★ Compliance and business ethics
- ★ Risk management
- ★ Corporate governance
- ★ Data privacy and cybersecurity
- ★ Intellectual property rights

Manage 14 highly significant topics:

Five task forces' responsibilities, concerns on sustainability, and the corresponding SDGs

Corresponding SDGs	Taskforce	Responsibilities	Topics
  	Environmental Friendliness Taskforce	Identifying and managing the life cycle stages of PharmaEssentia's products that may have an impact on the environment, such as energy use, water resource use, greenhouse gas emissions, medical waste management, chemical substance management, etc.	<ul style="list-style-type: none"> ★ Waste management ★ Toxic chemical substance management
 	Employee care Taskforce	Managing the topics of each stage of the human resource cycle of PharmaEssentia, including recruitment, appointment, compensation assessment, rewards, training, performance assessment, employee assistance, workplace health and safety, resignation and retirement, etc.	<ul style="list-style-type: none"> ★ Occupational health and safety ★ Talent cultivation and career development
  	Corporate Governance Taskforce	Facilitate practical management functions of the Board of Directors: <ul style="list-style-type: none"> • Ensure compliance and business ethics. • Monitor operational risks. • Enhance the transparency and timeliness of public information. • Maintain sound financial performance. • Protect privacy and cybersecurity of the patients. • Construct a complete intellectual property rights application, acquisition, management, and operation. 	<ul style="list-style-type: none"> ★ Compliance and business ethics ★ Risk management ★ Corporate governance ★ Data privacy and cybersecurity ★ Intellectual property rights
  	Product Quality and Patient Safety Taskforce	Managing topics related to the life cycle (including R&D, clinical, manufacturing, and sales) safety, effectiveness, ethics, and morals of PharmaEssentia products.	<ul style="list-style-type: none"> ★ Patient safety ★ Product quality and safety management ★ Stable and secure supply chain
   	Access to Medicine Taskforce	Ensuring that patients have better rights and access to drugs, including policy participation, innovative technologies, ability building, and other aspects, consider how to assist patients in obtaining the medications they need and formulating relevant action plans to exert social influence in the medical field.	<ul style="list-style-type: none"> ★ Access to medicine ★ Innovative drugs research and discovery

Executive Center for Corporate Sustainability 2020 Management Effectiveness

Established the Execution Center for Corporate Sustainability for the first time and completed sustainability training for all employees in five taskforces.

Voluntarily released the first Sustainability Report in English and Chinese.

Completed identification of and responded to the concerns of stakeholders, including domestic and foreign investment corporations, on a total of 14 crucial ESG-related topics.

The first biotech, a pharmaceutical company in Taiwan, focuses on the strategic direction of “Access to medicine” and developing the Company’s sustainable development project: the Health and Human Rights Practitioner Project.

Following the sustainability asset review and planning, at the end of 2020, to continuously optimize the implementation of the sustainability project, the Execution Center for Corporate Sustainability worked with the 5 taskforces and department heads to identify key ESG topics. We further conducted education and training based on the SMART principle so that each department could set more precise and measurable ESG goals for the short, medium, and long term. After the target was established, to reduce possible obstacles and prevent other risk factors in the process of achieving the target performance, we introduced the COSO enterprise risk management framework as an education and training for all employees on ESG risk management identification, impact assessment, and countermeasures, and to identify 18 ESG non-financial risk topics based on the actual operation profile by the end of 2020. This served as the blueprint basis for PharmaEssentia’s sustainable development and defined our sustainable risk management actions to reduce the damage caused by risks or find new opportunities from them.



2020 goals and results of Execution Center for Corporate Sustainability, PharmaEssentia

Goals		Achievement and Results
Organization establishment and training	Establish Execution Center for Corporate Sustainability	<ul style="list-style-type: none"> “Execution Center for Corporate Sustainability of PharmaEssentia” was established in July 2020. Designated 1 director, one deputy director, and one executive secretary of the center
	Recruit and cultivate internal Sustainability Seed employee	<ul style="list-style-type: none"> 17 internal employees from 11 different departments were recruited as team members of the Sustainable Development Execution Center. Organized more than 100 cross-departmental internal meetings to meet consensus among the Company.
	Sustainability project initiation meeting and education training	<ul style="list-style-type: none"> The “PharmaEssentia Sustainable Development Project Initiation Meeting and Training” was held in April 2020. A total of 5 executives and more than 50 employees participated in the video conference.
Review of the sustainable assets and topics	Interviews with senior management and departmental supervisors	<ul style="list-style-type: none"> In 2020, more than 20 interviews were conducted with executives and departmental supervisors.
	Identifying stakeholders and materiality topics	<ul style="list-style-type: none"> Identified 11 types of stakeholders through interviews with executives and departmental. Identified 14 highly significant priority topics concern through 203 online questionnaires.
	Identifying non-financial risk topics	<ul style="list-style-type: none"> Conducted one training session on risk identification, with more than 50 participants from executives and department heads, and 2 workshops with more than 30 participants from each of the 5 taskforces. Identified 18 ESG non-financial risk topics.
Disclosure of sustainable information	Prepare and publish sustainability reports	<ul style="list-style-type: none"> The first Chinese version of the Sustainability Report of PharmaEssentia was published in September 2020. The first English version of the Sustainability Report of PharmaEssentia was published in December 2020.

2-2

Corporate governance and management

Materiality Topic

Management approach on corporate governance

GRI 103-2

GRI 103-3

Top 6%-20%

The target was reached ahead of schedule in 2020, moving towards the 5% range.

The Financial Supervisory Commission (FSC) joined the spirit of ESG in 2020. It released a 3-year plan to promote Taiwan's "Corporate Governance 3.0 - A Blueprint for Sustainable Development," which will include 5 main axes and a total of 39 specific measures to create a sound ecosystem for ESG sustainable development. In addition to reviewing operations through the corporate governance assessment, PharmaEssentia also incorporated sustainable development as the corporate development strategy and incorporated it into the key development direction of corporate governance.



Policies

Internal Policy

- Corporate Governance Code
- Codes of Ethical Conduct
- Principles of Ethical Corporate Management
- Corporate Social Responsibility Best Practice Principles
- Procedures for Ethical Management and Guidelines for Conduct
- Rules and Procedures of the Board of Directors Meeting
- Regulations for the Self-Appraisal or Peer Appraisal of the Board of Directors
- Manager Performance Evaluation Regulations

External Compliance

- Corporate Governance 3.0 - Blueprint of Sustainable Development
- The relevant regulations established by the competent authorities to regulate the listed companies.



Commitments

Corporate governance is an essential foundation for a sound capital market and a key to attracting investors' continuous investment. We will refer to the new Corporate Governance 3.0 - Blueprint of Sustainable Development to improve the corporate governance management mechanism.



Responsibilities

- Audit Office, Management Team, Board of Directors, Audit Committee, Remuneration Committee
- Executive Center for Corporate Sustainability - Corporate Governance Taskforce



Resources invested

- The Company's Board of Directors authorizes the executive team to conduct execution and cooperates with relevant departments to promote the corporate governance code.
- External professional advisors, annual financial budgets related to the Group's departmental budgets, etc.
- Executive Center for Corporate Sustainability coordinates the inter-departmental units and subsidiaries of the head office to establish annual goals and strategies for sustainable ESG development.



Goals and targets

2021 Short-term Goals

1. Establish a Head of Corporate Governance to strengthen the regulatory function of the independence of the governance culture.
2. The Board of Directors and the management team are scheduled to attend at least two training courses per year.
3. Introduce external professional organizations to evaluate the annual performance of the Board of Directors and board members.
4. Expand the scope of the sustainability report to the U.S. subsidiary and the Taiwan subsidiary.

2022~2024 Mid-term Goals

1. Promote the establishment of a nominating committee.
2. Expand the scope of the perpetual report to include subsidiaries in South Korea, Japan, and China.
3. Related party transactions for non-operating activities should be reported in the shareholders' meeting.
4. Refer to Task Force on Climate-related Financial Disclosures (TCFD) to enhance the sustainability report disclosure.
5. Announces self-closing financial information.
6. Improve domestic corporate governance ratings to within the top 5% (tier 1 range).
7. Increase the number of independent directorships to more than one-third.

2025 Long-term Goals

1. Promote the performance appraisal system of each functional committee to enhance the operational efficiency of each operating committee and obtain the corresponding remuneration.
2. Achieve corporate governance assessment results within the top 5% range and increase penetration of international sustainable investment institutions.



Mechanisms for evaluating the effectiveness of the management approach

Evaluation of Management mechanisms

Internal audit mechanisms:

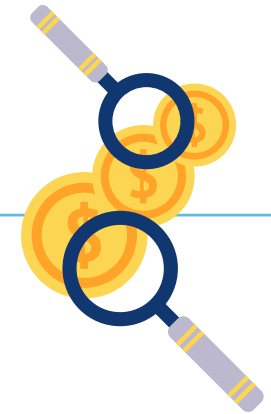
1. Comply with the competent authorities to regulate the appropriate methods.
2. Procedures for Handling Material Inside Information and Preventing Insider Trading
3. Conduct internal audits annually and regular quarterly reports to the Board of Directors on the results of implementation.
4. Review the goal setting and implementation of sustainability topics quarterly through Executive Center for Corporate Sustainability and other task forces.
5. There is an investor relations area and an interactive area for investors on the official website.

External audit mechanisms:

1. Financial Supervisory Commission's evaluation of corporate governance.
2. Introduce an external professional organization for performance evaluation of the Board of Directors and board members.
3. Introduce third-party verification of sustainability report.
4. Include results of quarterly or annual reports issued by foreign ESG rating professional institutions.

2020 Evaluation Results

- One case of deficiency in internal audit, and the improvement has been 100% completed.
- Results of self-evaluation by the Board of Directors: There is nothing needed to be improved.
- Submitted the Company's quarterly financial statements to the Audit Committee for concurrence from the second half of 2020.
- Electronic voting has been implemented at shareholders' meetings.
- Domestic and international index constituents, such as MSCI Taiwan, TPEX 200 Index, TIP Taiwan Bio Index.
- Improved 2019 corporate governance ratings to top 6% to 20% range (tier 2).



Corporate governance improvement topics

Event /

In 2020, Taipei Exchange found that the Company failed to comply with the "Procedures for Verifying and Disclosing Material Information" and "Information Reporting Procedures" for listed companies and imposed a penalty of liquidated damages in five cases.

Method of Improvements /

In this regard, the Company has set up preventive measures to improve the situation through internal discussions of relevant departments' regulations and external training of experts on legal regulations, and reported to the Board of Directors. In addition, FSC corrected two deficiencies and requested the Company to correct without penalty in the future without penalty, and the Company completed the improvement within the deadline. As of the publication of this report, there have been no further incidents of negligence or penalties.

A specialized and diverse Board of Directors

GRI 102-18

GRI 405-1

The Board of Directors is the highest level of governance and consists of 11 directors. The Board of Directors meets at least once a quarter, with the manager and the treasurer present for the consultation, and the audit director was reporting to the Board of Directors on audits. 8 Board meetings were held in 2020 with an actual attendance rate of 97.7%. Significant Board resolution items for 2020 can be found on our [official website](#).

In response to the governance needs of sustainable development, Executive Center for Corporate Sustainability was established in 2020 in the governance structure, directly under the CEO, with regular business reports to the Board of Directors quarterly.

- 2** Female Directors
- 2** Executive Directors
- 3** Independent Directors

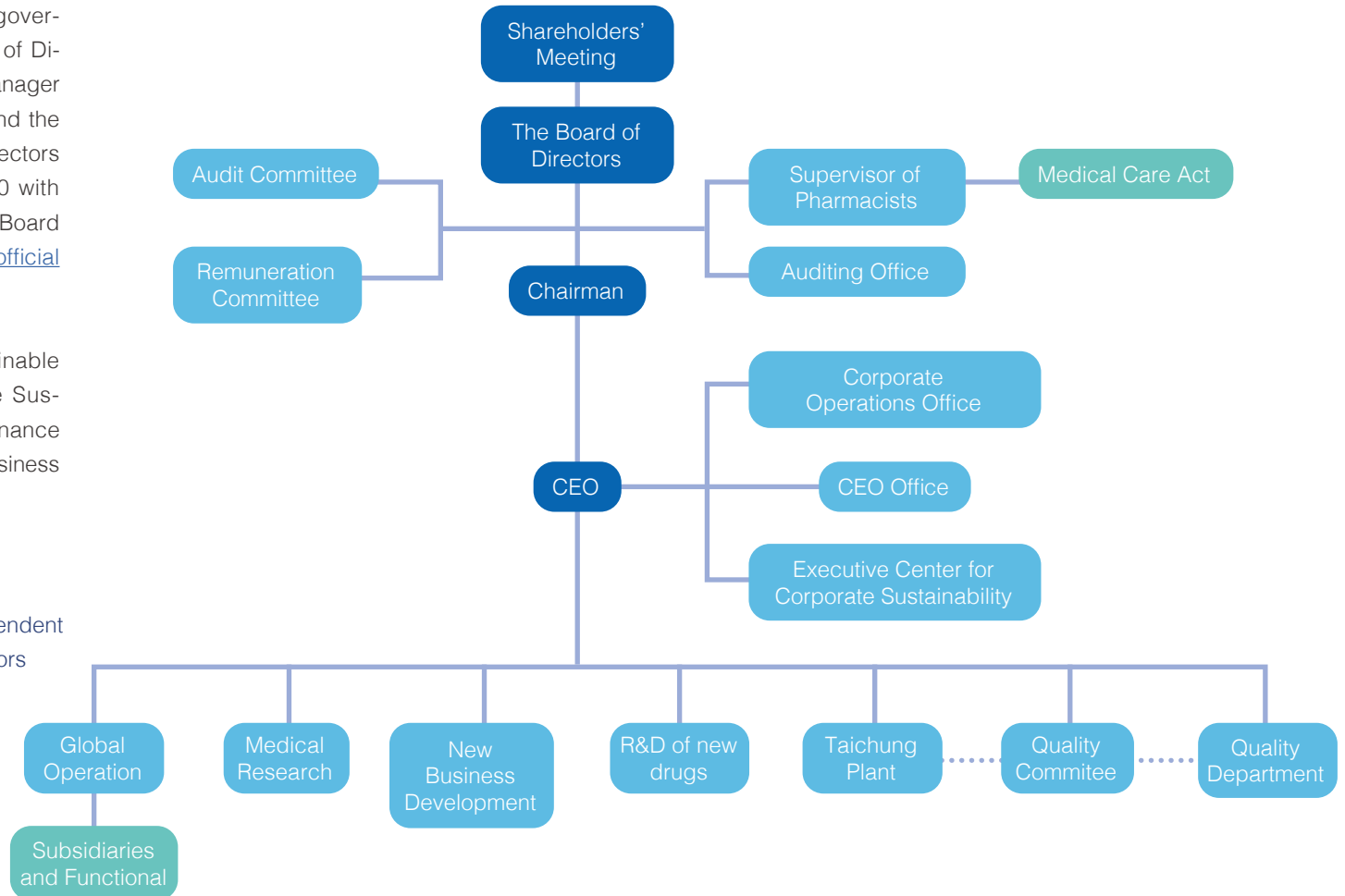


Figure 6: Governance Structure of PharmaEssentia

The Board of Directors is a critical player in setting the Company's sustainability strategy, overseeing management, and being accountable to the Company and shareholders. Pharma-Essentia has a policy of "[Diversified board members.](#)" aiming to provide members with different professional and industrial backgrounds and provide professional advice on operating judgment, accounting and analysis, operation management, industry knowledge, and international market outlook. The 11 seats of Directors include three seats of Independent Directors, accounting for 27.2% of the total number of Directors.

Board Member Diversity										
Directors	Gender	Age			Specialized knowledge and skills					
		51~60	61~70	71~80	Biotech	Electronics	Food	Education	Accounting/ Law	Marketing
Ching-Leou Teng	Female		●		●					
Chao-Ho Chen	Male			●		●				
Tian Chang	Male			●			●			
Ben-Yuan Chen	Male			●				●		
Lung-Chih Yu	Male	●			●					
Hui-Ping Wang	Female	●							●	
Jack Hwang	Male		●		●					
Shi-Ying Hsu	Male		●							●
Jinn-Der Chang*	Male			●					●	
Patrick Y. Yang*	Male			●	●					
Jien-Heh Tien*	Male		●		●					

Note 1: *= Independent Directors

Note 2: The information in the above table is the list of board members of the company as of December 31, 2020

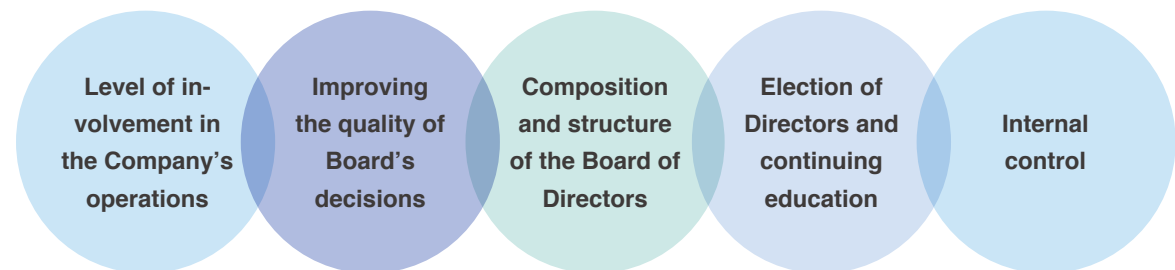
Functional committees

The Board of PharmaEssentia has set up two functional groups, “Audit Committee” and “Remuneration Committee,” by their authorities and functions to assist it in supervising the quality and integrity of the Company’s implementation of accounting, auditing, financial reporting processes, and financial control, and improving the compensation and remuneration mechanism of the Company’s Directors and managers. The functional committees of PharmaEssentia are composed of Independent Directors to ensure effectively implementing the supervision and checks and balances of operation of Independent Directors. PharmaEssentia plans to promote the establishment of a “Nomination Committee” in 2022 to jointly review the composition of directors and managers, improve the functions of the Board of Directors and strengthen the management mechanism.

	Audit Committee	Remuneration Committee
Responsibilities	Assist the Board in supervising the Company's performance quality and credibility in accounting, audit, financial reporting process, and financial control.	Assist the Board of Directors in formulating and reviewing the policies, systems, standards, and structures of performance evaluation and remuneration for directors, supervisors, managers, and managers.
Composition	Jinn-Der Chang (Independent Director), Patrick Y. Yang (Independent Director), and Jien-Heh Tien (Independent Director)	Jinn-Der Chang (Independent Director), Patrick Y. Yang (Independent Director), Jien-Heh Tien (Independent Director), and Ming-Chuan Hsieh (Professor)
Number of meetings	8	2
Attendance Rate	100%	100%

Board performance and self-evaluation

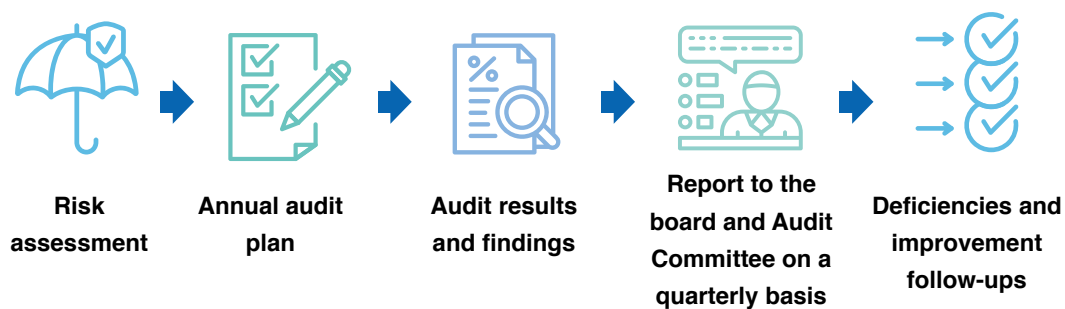
To implement corporate governance and enhance the functions of the Board of Directors, PharmaEssentia formulated the [“Regulations for the Self-Appraisal or Peer Appraisal of the Board of Directors”](#) to establish performance objectives and evaluation systems. The Board of Directors of PharmaEssentia shall perform internal Board performance evaluation at least once a year and appoint an external professional independent organization to conduct a performance evaluation of the Board at the end of the current year in the frequency of every three years. The performance evaluation measures include at least the following five significant aspects:



In February 2021, the Directors of PharmaEssentia have completed the 2020 performance evaluations of the Board and its members by internal self-evaluation. According to the results of self-evaluation in 2020, there is nothing needed to be improved.

Internal controls and auditing

The audit office of the Company is directly subordinated to the Board of Directors with two full-time auditors and duty representatives. It prepares an audit report based on factual records of internal control deficiencies and abnormalities found in audit work. The auditors report to the Audit Committee and the Board of Directors on the quarterly execution of the audit operations. Through routine and ad hoc inspections, the internal auditors grasp the operating status and potential risks of internal control functions and assist the Board of Directors and management to fulfill their responsibilities to implement the corporate governance system.



44

Completed audit report

1

Audit deficiency

100%

Completion rate of improvement on audit deficiencies

Annual operating results

GRI 201-1

Operating results in the last 3 years			
	2020	2019	2018
Total Sales Revenue	557,257	305,692	26,236
Total Operating Costs	373,323	61,703	28,394
Total Operating Expenses	1,899,786	1,093,212	1,052,732
Net Profit Before Tax	-1,948,016	-842,144	-1,039,168
Income Tax Expense	-126	-850	-592
Profit or Loss After Tax for the Period	-1,948,142	-842,994	-1,039,760
Other Comprehensive Income	-13,089	926	472
Total Comprehensive Income for the Year	-1,961,231	-842,068	-1,039,288

Unit: NT\$ thousands

Note: Above information is from the Company's consolidated financial statement.

2-3

Compliance and business ethics

Materiality Topic

Management approach on compliance and integrity management

Laws and regulations highly regulate the biotech and medical industry. Our products are sold in markets across Europe, the United States, and Asia, so we must comply with the laws and regulations of each country. Therefore, we keep abreast of any domestic or foreign policies and laws that may significantly impact our operations, manufacturing, and product launches and are working on a compliance strategy framework for our global operations to reduce operational risks caused by violations of laws. The strategic framework of legal compliance of PharmaEssentia is composed of four cornerstones: "Structure and Governance," "Policies and Actions," "Operation and Accountability," and "Culture and Education." These enable Pharmaessentia, its subsidiaries, and employees worldwide to make legal and ethical decisions and move towards the vision of sustainable operation.



Vision

Providing employees with relevant knowledge and tools to enable all employees worldwide to follow the laws and codes of ethics.

Culture and Education

Establishing a culture of legal compliance, resilience and entrepreneurship, and strengthening the education and training of new employees.

Policies and Actions

Formulating policies that cover the core areas of legal compliance, and at the same time meeting the needs of future operation and development, providing employees with precise regulations, and supporting innovation and reasonable decision-making.

Operation and Accountability

Establishing legal compliance procedures and fully implementing legal compliance monitoring and internal control; establishing key plans and partnerships to support and implement future product launch related activities.

Structure and Governance

Establishing a legal compliance plans that are suitable for product launch scale, and promote cooperation and consistency between the headquarters and the subsidiaries.

GRI 103-2

GRI 103-3



Policies

Laws and regulations highly regulate the biotechnology and medical industry. All of our business practices and all phases of our products' lifecycle value chain must comply with the laws and regulations of each country. The Company must establish proper legal compliance policies and documented management systems, implement employee orientation and training, and ensure compliance with laws and company policies in every operational activity before and after product launch.



Commitments

The Group places great importance on compliance and monitoring at all stages of the industry value chain. It expects the employees worldwide to implement the following four cornerstones as a commitment to sustainable development.

- “Structure and Governance”: Establish a global pre- and post-market compliance program for products.
- “Policies and Actions”: Develop core areas of compliance and sound policies.
- “Operation and Accountability”: Establish legal compliance procedures and fully implement control and accountability management.
- “Culture and Education”: Continuously conduct employee education and promotion to deepen the corporate spirit.



Responsibilities

- The Board of Directors of the headquarter, the regulatory unit, the legal affairs unit, the human resources unit, each functional department, the management team, and the legal compliance team of each subsidiary.
- Executive Center for Corporate Sustainability - Corporate Governance Taskforce



Resources invested

1. Each functional department of the Group headquarter, and subsidiary shall prepare the annual budget related to the compliance plan, which shall be reviewed by the finance department of the headquarter and submitted to the Board of Directors for approval.
2. Each functional department engages external professional consultants to guide legal compliance policies following the Group’s development needs.
3. Human resources input: headquarter’s regulatory and legal units, U.S. subsidiary’s compliance committee, and each subsidiary’s compliance staff.



Goals and targets

2021 Short-term Goal

1. Establish an inter-compliance committee within the Group to coordinate organizational procedures.
2. Establish the Group headquarters’ “Top Management Principles for Group Business Conduct and Ethics” and related detailed operational policy documents.
3. Advise senior executives team on establishing an international compliance committee to oversee the effectiveness of the global compliance program under the compliance committee and establish a reporting mechanism to manage the headquarters and subsidiary/Board of Directors.
 - Identify members of relevant business units.
 - Develop organizational protocols that outline the roles and responsibilities of members.
 - Convene committees and educate members on roles and responsibilities.
4. Establish an integrity management supervisory unit under the legal compliance committee.



Goals and targets

2022~2024 Mid-term Goals

1. Complete the consistency of the organizational procedures of the Group and each subsidiary's compliance committee.
 - Regularly update compliance policies and practices to help ensure communication and program oversight of the global compliance program.
 - Promote transparency among compliance committee members and provide opportunities to share better practices and lessons learned.
2. Facilitate strategic decision-making processes that incorporate input from functional compliance representatives to achieve compliance with laws and company policies in every operational activity.

2025 Long-term Goals

Establish a global compliance committee.

- Provide a global view of the compliance risk profile for each subsidiary.
- Facilitate cross-region identification of operational efficiency and prevent duplication of effort.
- Make decisions and develop the Group's global risk management strategy.
- Assist in the management of risk supervision of global legal compliance among various branches.



Mechanisms for evaluating the effectiveness of the management approach

Evaluation of Management mechanisms

Internal audit mechanisms:

- The Group headquarters has established the "Corporate Governance Code," the "Principles of Ethical Corporate Management," the "Codes of Ethical Conduct," the "Procedures for Ethical Management and Guidelines for Conduct," the "Corporate Social Responsibility Best Practice Principles," and the "Operating Procedures for Handling Material Nonpublic Information and Preventing Insider Trading" in compliance with the Code of Business Ethics and Ethical Integrity.
- The Group has established an internal control and audit management system and 45 operational rules at the headquarters, and 24 legal compliance policy documents at the U.S. subsidiary.

External audit mechanisms:

The ethical behavior and ethical integrity of business operations from the R&D to the commercialization stage are following the "Guideline for the Nonclinical Pharmacology/Toxicology Studies for Medicinal Products Applications," "GxP," "Declaration of Helsinki," "Medical Care Act," "Regulations for the Administration of Human Trials," "European and American Pharmacopoeia," "Taiwan Medical Care Act and Pharmaceutical Affairs Law," "Standards for Medicament Factory Establishments," "Regulations for Registration of Medicinal Products," "Regulations for Drug Safety Monitoring" and "WHO Ethical Standards."

2020 Evaluation Results

- The Company has 5 civil lawsuits that have been determined or are still pending, as described in the [2020 Financial Report and Annual Report](#).
- No incidents of corruption or harm to customer privacy in 2020.

PharmaEssentia's business activities in compliance with the law



Before the launch of new products

- Establish a compliance committee.
- Establish an anonymous reporting hotline.
- Establish compliance is the area in PharmaEssentia's headquarter (U.S. subsidiary has published a compliance manual).
- All employees have read and acknowledged the laws and regulations that should be followed for each function.
- Employee compliance training.
- Meal monitoring system for medical professionals.
- Business rules and operations for speaking engagements.

After the launch of new products



- Implement a transparent reporting system and training for all employees.
- Speaking engagements, advisory committees, medical professional meal monitoring, and auditing system.
- Implement the Advisory Committee compliance process and control measures.
- Other compliance policies and standard operating procedures, such as investigations, controls, employee disciplines.

Continue to deepen and promote ethical corporate management

Due to the nature of the industry, its products are vital to human safety and health, so we must adhere to the Principles of Ethical Corporate Management in every aspect of our operations and production. [The Company's Code of Integrity](#) promotes the objectives: specifications of anti-corruption, corporate social responsibility, trade secrets, and conflicts of interest. There will also be corresponding authorities in each specification to improve its departmental organization.

Specifications	Action Plan
Anti-corruption	Focus on prohibiting any form of bribery, whether direct or indirect and implementing this anti-corruption implementation plan.
Corporate Social Responsibility	Focus on sponsorship and corporate social responsibility, including all company financial activities related to sponsorship or charitable activities, including drug donations and research sponsorship programs.
Trade secrets	Business secrets are essential assets of R&D enterprises, and they must be proactively protected and managed to a degree no less than patent protection.
Conflict of interest	The Company shall conduct its business activities by the "Fair Trade Act, Company Act, and Securities and Exchange Act."

Specific actions to avoid conflicts of interest

PharmaEssentia's codes of conduct include: "Corporate Governance Code," "Code of Ethical Conduct," "Principles of Ethical Corporate Management," and "Rules of Procedure for Board of Directors Meetings," which stipulate the Board of Directors and other related interest avoidance systems. In recent years, many countries in Europe, the United States, and Japan have regulations that require the drafting of whistle-blowing plans to protect whistleblowers, which is helpful for risk detection, commitment display, and goodwill protection. In the future, PharmaEssentia will continue to understand this trend and take more active actions to meet the expectations of investors and other stakeholders.

Regulations to abide along the value chain

At each phase of the biotech and new pharmaceutical industry chain, some rules must be followed. PharmaEssentia must comply with local laws and regulations at each phase of the industrial chain, and arbitrary experiments, manufacturing, sales, and advertising are strictly forbidden.

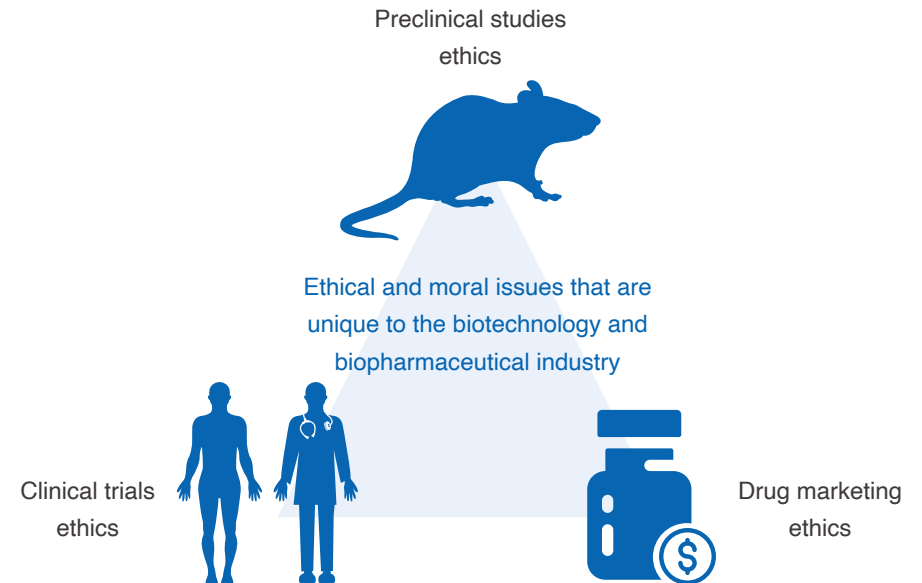
Specifications to be followed at each stage of the drug life cycle

R&D of new drugs and preclinical studies	Clinical trials	Manufacture and production	License application	Marketing and sales	Pharmacovigilance
<ul style="list-style-type: none"> GLP Guideline for the Nonclinical Pharmacology/Toxicology Studies for Medicinal Products Applications formulated by competent authorities of each country. 	<ul style="list-style-type: none"> GCP GMP Ethical principles from the Declaration of Helsinki Regulations formulated by local competent authorities. For example: the Regulations on Human Trials and the Pharmaceutical Affairs Act in Taiwan. 	<ul style="list-style-type: none"> GDP GMP Regulations formulated by local competent authorities. For example: the European Pharmacopoeia, United States Pharmacopeia, and the Medical Care Act, Pharmaceutical Affairs Act, and Standards for Medicament Factory Establishments of Taiwan. 	<ul style="list-style-type: none"> Regulations formulated by local competent authorities. For example: the Regulations for Registration of Medicinal Products in Taiwan. 	<ul style="list-style-type: none"> GDP Codes of Ethics formulated by the World Health Organization (WHO) and other countries. 	<ul style="list-style-type: none"> GVP Regulations formulated by local competent authorities. For example: Regulations for Drug Safety Monitoring in Taiwan.

Compliance with ethical standards of our employees

GRI 102-17

PharmaEssentia and all employees must abide by the company's 6 primary business conduct and ethics regulations. The human resources unit will promote the precautions related to professional ethics during the training of new employees. Following this spirit, we pay special attention to implementing ethical and moral standards in the 3 stages of the product life cycle, including preclinical animal experiment, human clinical trial, and drug marketing, on ethical and moral topics specific to biotechnology and pharmaceutical industries.



SASB HC-BP-270a.2



Preclinical studies ethics

Code of ethics and norms

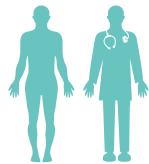
- Guideline for the Nonclinical Pharmacology/Toxicology Studies for Medicinal Products Applications formulated by competent authorities of each country. Non-Clinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals formulated by the ICH.
- GLP

Our actions

1. Establishing the Institutional Animal Care and Use Committee (IACUC) to review and supervise the situation of animal experiments and animal husbandry conducted by the institutions.
2. All CROs for animal experiments must pass domestic and foreign GLP certification.
3. Animals used in experiments must be healthy, free from sources of infection animals that meet the requirement level of Specific Pathogen Free (SPF), to prevent interference to trial results for certain diseases.
4. Actively implementing the 3Rs of laboratory animals: "Replacement," "Reduction" and "Refinement."

Our purpose

Ensuring that researchers follow relevant laws and regulations during animal experiments and minimize the use of laboratory animals.



Clinical trials ethics

Code of ethics and norms

- Clinical Study Policy formulated by the Company
- Declaration of Helsinki
- GCP
- Investigational new drug (IND) applications and local laws and regulations

Our actions

1. Establishing standard operating procedures for the formulation and approval of IND indications and subjects' informed consent.
2. All IND indication and informed consents of subjects must be reviewed and approved by the health authority and the "Institutional Review Board" before the start of the trial.
3. Subjects of clinical trials led by PharmaEssentia are insured with clinical trial insurance to protect their personal rights.
4. Personal data and privacy will be protected during the clinical trials.
5. Regular monitoring and auditing are also conducted during the clinical trials.

Our purpose

Ensuring that the safety, privacy, and other rights of clinical trial subjects are not violated, showing that the Company is a trustworthy biopharmaceutical company among patients.



Drug marketing ethics

Code of ethics and norms

- Code of Ethics formulated by the WHO, the National Council for Prescription Drug Programs (US), International Research-Based Pharmaceutical Manufacturers Association (Taiwan), National Council for Prescription Drug Programs (US), and the Foreign Corrupt Practices Act (US).
- The HCP& HCO Interaction Policy and the Promotional Material Policy formulated by the Company.

Our actions

1. All employees must follow the aforementioned ethical standards when interacting with people or organizations related to healthcare.
2. Marketing activities must be transparent, ethical, correct, balanced, and must not be misleading.
3. Marketing materials must include correct product risks and benefit assessments and appropriate usage methods.
4. It is not allowed to sell and market products in the name of clinical trials

Our purpose

Ensuring that medical staff obtains the necessary information, protect the medical care and wellbeing of patients, and implement the Company's mission and responsibilities in an ethical manner.

2-4

Risk and crisis management

Materiality Topic

Management approach on risk management

The Board of Directors is the highest supervisor and decision-maker of risk management, approves and implements the Company's overall risk management objectives and policies, continuously monitors the effective operation of the risk management mechanism, and is responsible for the ultimate responsibility of risk management of the Company. The Audit Committee has also been established to assist the Board of Directors in controlling existing or potential risk topics of the Company and strengthening the company's internal control mechanism. The Company has established appropriate policies, procedures, and internal control systems following relevant regulations. The Board of Directors must review significant financial activities following applicable laws and internal control systems. It is audited regularly and irregularly by the Audit Office and reported to the Board of Directors. In addition, before the Company formally establishes the risk control management committee, the Executive Center for Corporate Sustainability will initially be responsible for coordinating the identification of ESG non-financial risk topics. The managers of each functional unit will propose risk response measures following actual operations to control the possibility and impact of various business risks within a tolerable range, protecting the rights of multiple stakeholders of PharmaEssentia, and enhancing the sustainable value of the Company.

GRI 103-2

GRI 103-3



Policies

Internal Policy

- QRM - Procedure for Quality Risk Management of each relevant department.
- Corporate Governance Code
- Regulations Governing the Scope of Responsibilities of Independent Directors
- Audit Committee Organizational Procedures
- Corporate Social Responsibility Best Practice Principles
- Internal Control and Audit System and Management

External Compliance

- Corporate Governance 3.0-Blueprint of Sustainable Development Evaluation Index
- Regulations Governing the Exercise of Powers by Audit Committees of Public Companies



Commitments

Under the global competition, risk management is closely related to the core interests of enterprises. The 5 elements and 20 principles of COSO's "Enterprise Risk Management Framework" are introduced to help organizations consider the importance of risk in setting strategies and driving performance, and to achieve the objectives of "strengthening corporate resilience," "providing a common language for ESG risks," "optimizing resource allocation," "identifying and mastering ESG-related opportunities," "achieving economies of scale," and "improving information disclosure transparency" with considering the importance of risks.



Responsibilities

- The management team, the Board of Directors, the audit committee, the audit office, and all functional departments of the Group headquarter and subsidiaries.
- Executive Center for Corporate Sustainability- 5 major taskforces



Resources invested

1. The audit office prepares an annual internal audit plan and audit budget and performs risk management according to the internal control and audit system.
2. Hire external sustainability consultants for COSO project coaching.
3. Executive Center for Corporate Sustainability and 5 taskforces with about 50 members to coordinate cross-departmental units to introduce ESG risk management training on the identification, impact assessment, and countermeasures.
4. The Executive Center for Corporate Sustainability recommends or assists in developing non-financial, ESG-related plans and budgets as needed.



Goals and targets

2021 Short-term Goals

1. Promote a risk management committee or risk management team to develop risk management policies at the corporate level.
2. Introduce a non-financial ESG risk management program.
3. Introduce an external third-party validation unit for sustainability report audits.

2022~2024 Mid-term Goals

1. Report to the Board of Directors for approval of establishing risk management committee and implementing a risk management mechanism through COSO 2017 ERM or "ISO 31000: Risk Management."
2. The risk management mechanism can be extended to the Group's subsidiaries.
3. Continue to conduct risk management education and training for the Board of Directors, supervisors at all levels, and employees to strengthen risk management awareness and integrate into daily work operations.

2025~ Long-term Goals

- Continue to strengthen the Board of Directors, executives at all levels, and employees of the Group's companies to grasp and deepen their awareness of risk management to respond to dynamic adjustments in the general environment at any time and pursue corporate sustainability.



Mechanisms for evaluating the effectiveness of the management approach

Evaluation of Management mechanisms

Internal audit mechanisms:

- Introduce COSO Enterprise Risk Management Framework for internal management purposes.
- Regulations for the Self-Appraisal or Peer Appraisal of the Board of Directors
- Manager Performance Evaluation Regulations
- An annual internal audit plan

External audit mechanisms:

- Corporate Governance 3.0 sustainable development assessment indicators
- External corporate evaluation of the performance of the Board and the Board members
- Import Sustainability report to the third-party certification institute.
- Foreign professional ESG rating agencies issue quarterly or annual rating reports.







2020 Evaluation Results

- 1 case of deficiency in internal audit, and the improvement has been 100% completed.
- The internal audit supervisor regularly reports to the Board of Directors quarterly, and the independent directors communicated with the supervisor of internal audit and the accountant 7 times in 2020, and there were no other recommendations.

PharmaEssentia's risk management structure

GRI 102-11 GRI 102-15

Based on the ESG materiality topics identified in this report and their professional observations of the Company's operations, the Executive Center for Corporate Sustainability of ParmaEssentia and members of the cross-departmental functional groups evaluate the risk events that may have an impact on business objectives in terms of the "likelihood of occurrence" and "impact after occurrence" of ESG risks. In the future, ParmaEssentia will continue to optimize the risk management mechanism to reduce the impact of wagers on the Company.

Unit/ Role	Responsibility
 <p>The Board of Directors</p>	<p>Highest directing unit for risk management of the Company and to supervise, review and approve the effectiveness of the risk topics and essential risk management mechanisms that may be faced by the operations of the head office and each subsidiary.</p>
 <p>Audit Committee</p>	<p>Assist the Board of Directors in controlling the Company's existing or potential risk topics and strengthen the company's internal control mechanism.</p>
 <p>Auditing Office</p>	<p>Prepare annual audit plans following the Company's risk management policies and systems, conduct independent audits, and submit audit reports to the Board of Directors and Audit Committee quarterly.</p>
 <p>CEO</p>	<p>As the chief convener, coordinates the management team of Taiwan headquarters and subsidiaries and the measurement, execution, and control of each department's risk management.</p>
 <p>Executive Center for Corporate Sustainability and 5 taskforces</p>	<p>Assist the Company in assessing the impact of ESG-oriented non-financial risk topics on sustainable operations, preparing preliminary actions to address them, and submitting business reports to the Board of Directors every quarter by representatives of the Executive Center for Corporate Sustainability.</p>
 <p>Each functional department</p>	<p>The department manager conducts risk identification, impact assessment, analysis, and evaluation, identifies countermeasures and improvement measures according to the department's job description, and conducts education and promotion of risk awareness management to employees in daily operations.</p>

Note: Please refer to [section 2.2, "Figure 6: ParmaEssentia's Governance Structure"](#) for ParmaEssentia's risk management organizational chart.

Identification of non-financial risk topics

The Committee of Sponsoring Organizations of the Treadway Commission (COSO) and the World Business Council For Sustainable Development (WBCSD) published the Corporate Risk Management Framework in 2018. We will identify the non-financial risk topics of PharmaEssentia from the perspective of understanding the likelihood and impact of risks through an organized and structured COSO and plan management mechanisms and future action plans. Our process for identifying non-financial risk topics is described below.

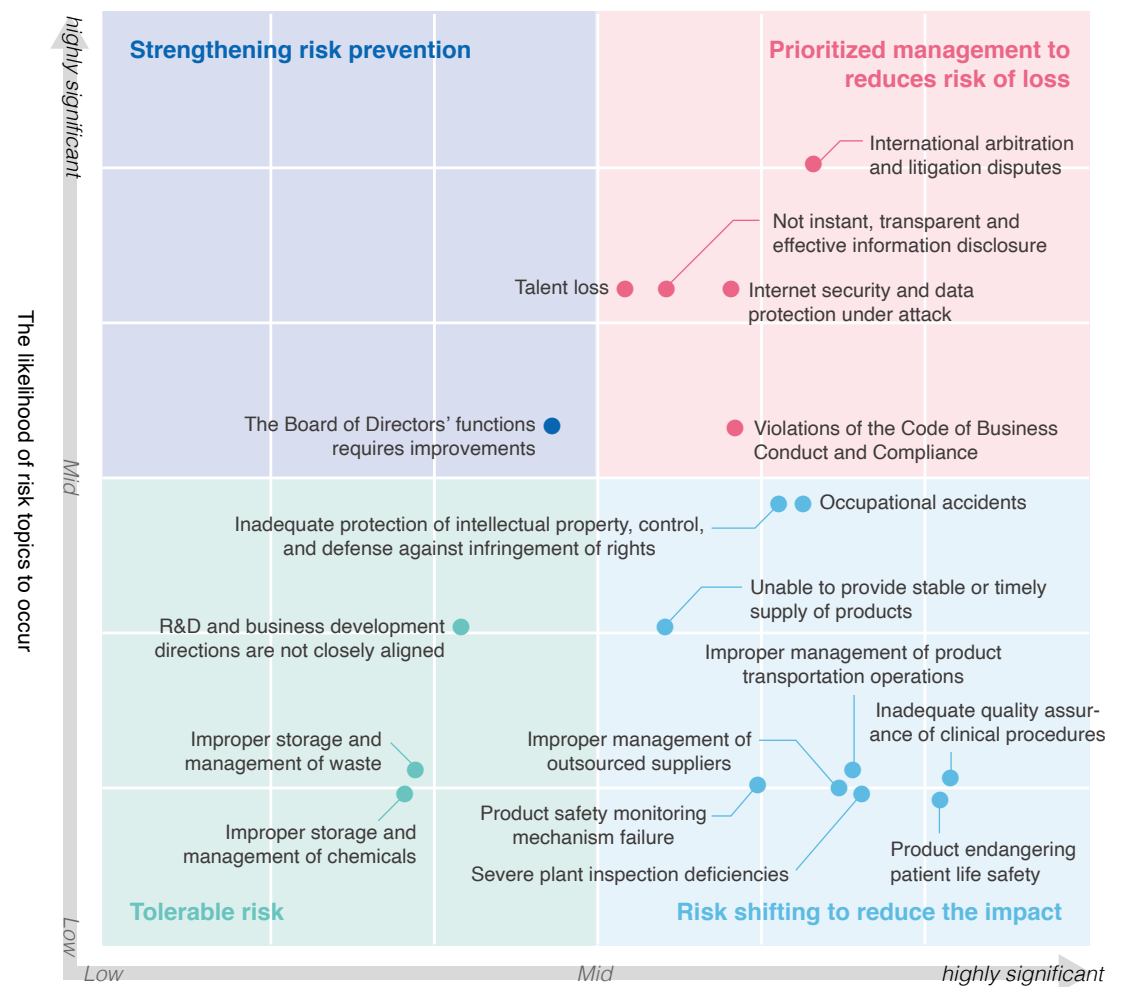
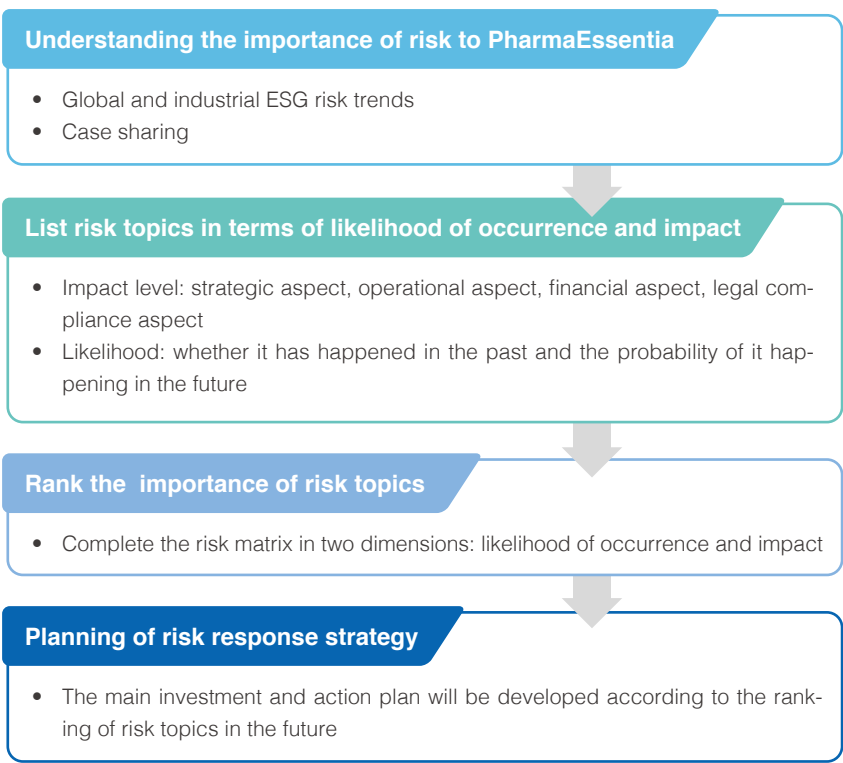








Figure 7: PharmaEssentia non-financial risk matrix.



Existing management mechanism and future enhancement actions for non-financial risk topics of PharmaEssentia

Number	Risk topics	Corresponding Highly Significant Topics	Existing Management Mechanisms	Future Optimized Actions
1	Occupational accidents	Occupational health and safety for more information, please refer to section 4.5	<ol style="list-style-type: none"> 1. Set the procedure for each unit to implement. 2. Enforce following the Occupational Safety and Health Law. 3. Routine inspection by environmental safety units. 4. Maintain facilities annually. 	<ol style="list-style-type: none"> 1. Hold occasional educational training. 2. Hire a consultant to review the hazardous area and explosion-proof zone of the production area and improve plans. 3. Replace safety facilities and implement preventive safety measures. 4. Introduce ISO45001 2018 Occupational Safety and Health Management System.
2	Talent loss	Talent cultivation and career development for more information, please refer to section 4.3	<ol style="list-style-type: none"> 1. Employee compensation mechanism. 2. Annual salary adjustment and promotion mechanism. 3. Training courses to enhance competency. 4. Implement new programs or projects and provide learning opportunities. 	<ol style="list-style-type: none"> 1. Improve the working environment and welfare system of employees. 2. Establish a talent development system and implement phased talent development and retention plan. 3. Plan and establish knowledge and experience transfer mechanisms to reduce the risk of technology and experience loss. 4. Establish a succession system.
3	Improper storage and management of chemicals	Toxic chemical substance management for more information, please refer to section 5.3	<ol style="list-style-type: none"> 1. Follow the period of reporting the operation volume according to the competent authority. 2. Handle the disposal of chemicals and waste by the internal chemical and waste management procedures. 3. Join the regional poison disaster prevention organization. 	<ol style="list-style-type: none"> 1. Strengthen the agent system. 2. Strengthen employee education and training to enhance risk awareness. 3. Timely adjust plant management measures and programs in response to regulatory amendments. 4. Disclose the annual greenhouse gas emissions, water consumption, and total weight of waste in the past two years. 5. Introduce ISO 14001 EMS.
4	Improper storage and management of waste	Waste management for more information, please refer to section 5.2	<ol style="list-style-type: none"> 1. Follow the period of reporting the operation volume according to the competent authority. 2. Handle disposals by internal waste management procedures. 	
5	Product endangering patient life safety	Patient safety for more information, please refer to section 3.6	<ol style="list-style-type: none"> 1. Ensure complete collection of safety information through various adverse drug event reporting channels disclosed on the Company's official website. 2. Accurately report serious adverse events. 	<ol style="list-style-type: none"> 1. Take the initiative to inform hospital physicians and medical staff of the free service number and email address for product safety notification. 2. Proactively ask physicians and healthcare professionals if they have any serious adverse events.

Number	Risk topics	Corresponding Highly Significant Topics	Existing Management Mechanisms	Future Optimized Actions
6	Product safety monitoring mechanism failure	Patient safety ✚ for more information, please refer to section 3.6	<ol style="list-style-type: none"> 1. Regularly confirm the number and items of security incidents reported by CROs. 2. Regularly confirm with subsidiaries the items and quantity of security incident notifications. 	<ol style="list-style-type: none"> 1. Annually review CRO execution capabilities. 2. Continue to monitor the execution capability of our subsidiaries.
7	Severe plant inspection deficiencies	Product quality and safety management ✚ for more information, please refer to section 3.3	<ol style="list-style-type: none"> 1. Each internal department shall undergo an internal quality audit every year. 2. According to demand, foreign experts are invited to conduct quality audits when necessary. 	We continue to optimize and improve the quality system (including inviting domestic and foreign experts to review and optimize existing systems, such as optimizing abnormal incident handling and investigation systems).
8	Improper management of product transportation operations	<ul style="list-style-type: none"> • Product quality and safety management ✚ for more information, please refer to section 3.3 • Stable and secure supply chain ✚ for more information, please refer to section 3.1 	<ol style="list-style-type: none"> 1. Strictly control the packing process and transportation process to ensure that the products are kept within the temperature range of 2°C to 8°C and maintain the required refrigeration equipment. 2. Follow the GDP requirements. 	<ol style="list-style-type: none"> 1. Establish supporting evidence for the allowable time out of temperature to increase operational flexibility. 2. Execute external audit plan.
9	Unable to provide a stable or timely supply of products	<ul style="list-style-type: none"> • Stable and secure supply chain ✚ for more information, please refer to section 3.1 • Access to medicine ✚ for more information, please refer to section 6.1 	<ol style="list-style-type: none"> 1. Pre-plan and confirm production scheduling. 2. Establish safety stock level and the second source of the material. 3. Coordinate and arrange the transportation operation according to the temperature layer of the drug demand. 4. The quality assurance unit ensures that the relevant documents and operations meet the standards for product release. 5. Quarterly commercial and clinical development demand estimation mechanism. 6. Risk management policy. 7. Raw material management policy. 8. Drug safety notification system of the competent authorities of each country. 9. Shortage notification system of competent authorities of each country. 10. The drug complaint system established by the PEC. 	<ol style="list-style-type: none"> 1. Electronic scheduling system. 2. Plant expansion. 3. Process improvement. 4. Disseminate PharmaEssentia's philosophy of sustainability, promote and sign the supplier code of conduct. 5. Seize information to respond to market changes quickly. 6. Strengthen supplier management capability, close and strengthen the interaction with suppliers. 7. Prioritize critical materials for evaluation, screen out candidates, conduct quality confirmation, and develop the second sources of material.

Number	Risk topics	Corresponding Highly Significant Topics	Existing Management Mechanisms	Future Optimized Actions
10	Improper management of outsourced suppliers	Stable and secure supply chain  for more information, please refer to section 3.1	<ol style="list-style-type: none"> 1. Establish a supplier evaluation mechanism. 2. Perform various validation and verification. 3. External audit program. 4. Sign supply or quality contracts. 5. Provide outsourced CMO demand estimation plan and update promptly. 6. Establish contact channels with outsourcing companies to review relevant quality events and decide on real-time follow-up actions. 7. Commissioning activity policy. 8. Product packaging and identification policy. 	<ol style="list-style-type: none"> 1. Disseminate PharmaEssentia's philosophy of sustainability, and promote and sign the supplier code of conduct. 2. Seize information to respond to market changes quickly. 3. Strengthen supplier management capability, tightness and strengthen the interaction with suppliers. 4. Prioritize critical materials for evaluation, screen out candidates, conduct quality confirmation, and develop the second sources of material.
11	Inadequate quality assurance of clinical procedures	<ul style="list-style-type: none"> • Product quality and safety management  for more information, please refer to section 3.3 • Access to medicine  for more information, please refer to section 6.1 	Execute the management method according to the existing QA department and QA system.	Add other GxP-related quality assurance personnel, standard operating procedures, monitoring mechanisms, or systems for outsourcing audit activities.
12	Violations of the code of business conduct and compliance	<ul style="list-style-type: none"> • Compliance and business ethics  for more information, please refer to section 2.3 • Access to medicine  for more information, please refer to section 6.1 	<ol style="list-style-type: none"> 1. The "Corporate Governance Code," the "Principles of Ethical Corporate Management," the "Code of Ethical Conduct," the Procedures for Ethical Management and Guidelines for Conduct," the "Corporate Social Responsibility Best Practice Principles," and the "Operating Procedures for Handling Material Nonpublic Information and Preventing Insider Trading" are in place. 2. The Group has established internal control and audit management system and 45 operational management rules at the headquarters, and 24 legal compliance policy documents at the U.S. subsidiary. 3. The business ethics and integrity of business conduct from research and development to the commercialization stage must comply with external regulations. 	<ol style="list-style-type: none"> 1. Establish the "Group's Business Code of Conduct and Ethics Top Management Principles" at the Group headquarter. 2. Establish an integrity management supervisory unit responsible for the formulation and supervision of the implementation of integrity management policies and prevention programs and report to the Board of Directors at least once a year on the operation and performance of such policies.
13	R&D and business development directions are not closely aligned	Innovative drugs research and discovery  for more information, please refer to section 1.3	<ol style="list-style-type: none"> 1. Research and develop internal control rules and regulations and related management methods. 2. Mechanisms and training of due diligence. 	<ol style="list-style-type: none"> 1. Implement the training and execution of existing standard operating procedures. 2. Management Steering Committee co-determination mechanism. 3. Establish the evaluation process of R&D and business requirements.

Number	Risk topics	Corresponding Highly Significant Topics	Existing Management Mechanisms	Future Optimized Actions
14	Inadequate protection of intellectual property, control, and defense against infringement of rights	<ul style="list-style-type: none"> Intellectual property rights for more information, please refer to section 2.6 Compliance and business ethics for more information, please refer to section 2.3 	<ol style="list-style-type: none"> Intellectual property rights management and utilization method. Corporate legal affairs and lawyers. Corporate Governance Code Internal control and audit system and management methods. 	<ol style="list-style-type: none"> Innovative reward system. Abandon access to specific countries' markets if necessary. Introduction and implementation of FTO (Free to Operate). Join a marketing system to detect infringement mechanisms. Mechanism and training for due diligence on technologies of interest to acquire. Increase the strength of contract gate-keeping. Education and training. Establish an audit mechanism so that the system can be checked promptly. Data storage equipment management.
15	Cybersecurity and data privacy protection	<p>Data privacy and cybersecurity</p> <p>for more information, please refer to section 2.5</p>	<ol style="list-style-type: none"> Firewall, antivirus software. Part of the equipment has been updated. 	<ol style="list-style-type: none"> System upgrade. Formulate various methods to maintain cybersecurity norms. Infiltration test. Vulnerability scanning. Only use the USBs with the Company's approval. Publicity and educational training. Data storage equipment management.
16	International arbitration and litigation disputes	<p>Corporate governance</p> <p>for more information, please refer to section 2.2</p>	<ol style="list-style-type: none"> Audit Committee. FSC corporate governance evaluation system indicators. Board of Directors and director evaluation mechanism. Internal auditing operations. In compliance with the competent authorities to regulate, the appropriate methods have been developed. Internal material information handling and prevention of insider trading management procedures. Please refer to the public information observation post system, the Company's official website, the 2020 annual report, and financial statements for more information. 	<ol style="list-style-type: none"> Implement the FSC's Corporate Governance 3.0 Sustainable Development Blueprint evaluation indicators. Set up the head of corporate governance to increase the independence of supervision. Introduce enterprise risk management mechanism. Add functional committee. Strengthen the roles and functions of independent directors and the audit committee. Introduce external evaluation body institution of the Board of Directors. Please refer to the public information observation post system, the Company's official website, the 2020 annual report, and financial statements for more information.

Number	Risk topics	Corresponding Highly Significant Topics	Existing Management Mechanisms	Future Optimized Actions
17	The Board of Directors' functions requires improvements	Corporate governance  for more information, please refer to section 2.2	<ol style="list-style-type: none"> 1. Audit Committee. 2. FSC corporate governance evaluation system indicators. 3. Board of Directors and director evaluation mechanism. 4. Internal auditing operations. 5. Irrelevant methods in compliance with the competent authorities have been developed. 6. The appointment and removal of the internal audit supervisor shall be approved by the Board of Directors. 	<ol style="list-style-type: none"> 1. Implement the FSC's Corporate Governance 3.0 Sustainable Development Blueprint evaluation indicators. 2. Set up the head of corporate governance to increase the independence of supervision. 3. Introduce enterprise risk management mechanism. 4. Add functional committee. 5. Strengthen the roles and functions of independent directors and the audit committee. 6. Introduce board members with ESG backgrounds. 7. Diversification of the Board of Directors' education program. 8. Introduce external evaluation institution of the Board of Directors. 9. Set up the operating rules for the appointment and dismissal of internal audit supervisors, internal audit staff, appraisal, and salary and compensation sign-off. 10. At least one of the Company's internal auditors has the certification of international internal auditor, international computer auditor, or passing an accounting examination.
18	Not instant, transparent and adequate information disclosure not instant, transparent and effective information disclosure	Corporate governance  for more information, please refer to section 2.2	<ol style="list-style-type: none"> 1. Internal material information handling and prevention of insider trading management operational procedures. 2. Significant information specified by the competent authority for verifying and disclosing important information of listed (counter) companies. 3. Matters to be announced or reported under regulations authorized by Article 36-1 of the Securities and Exchange Act. 4. Range prescribed in the Regulations Governing the Scope of 4 Material Information and the Means of its Public Disclosure Under Article 157-1 of the Securities and Exchange Act. 5. Items stipulated in Article 7 of the Securities and Exchange Act Enforcement Rules. 	<ol style="list-style-type: none"> 1. Strengthen the promotion of all staff and implement the quality of financial information disclosure. 2. Implement relevant regulations in compliance with the rules of the competent authority. 3. Import the sustainability report into a third-party verification institution.

2-5

Rigorous data privacy and cybersecurity

Materiality Topic

Management approach on cybersecurity and data privacy protection

GRI 103-2 GRI 103-3 GRI 418-1



Cybersecurity

- Aim to establish a Cybersecurity Management Committee in 2021.
- Completing the ISO 27001: Information Security Management certification within 5 years.



Data privacy protection

- Strictly abide with the General Data Protection Regulation (GDPR) principles and requirements to protect the personal information of patients in clinical trials.
- Entrust qualified CROs to conduct clinical trials.
- The patient's personal information will only be stored in the experimental hospital, and the Company cannot identify the subject's personal data, nor can it obtain their personal data.

The Company is cautious in the management of cybersecurity, has established an information system cycle in the internal control system, and entrusts a professional information company that meets the ISO 27001: Information security management certification for the planning, implementation, maintenance, management, and support of the Company's information system. The Company has begun to prepare a self-organized information team. It will establish a Cybersecurity Management Committee in 2021 to strengthen cybersecurity risk control, complete ISO 27001 in 2025, and establish an effective cybersecurity management mechanism to enhance the cybersecurity awareness of all employees.



Policies

Internal Policy

- Internal control of information system cycle, R&D cycle (R&D information and document control operations).
- Management of protection of personal information

External Compliance

- Personal Data Protection Act
- EU's General Data Protection Regulation (GDPR)
- Good Clinical Practice (GCP)
- Declaration of Helsinki
- Human Research Ethics Policy Guidelines
- Medical Care Act



Commitments

- To protect the Company's business secrets and the Company's competitiveness in the development of new drugs, PharmaEssentia continues to improve the density of its confidential information management policy.
- Regarding the privacy and personal information of patients and employees, the Company abides by relevant policies and laws, and regulations to ensure the rights and interests of relevant stakeholders.



Responsibilities

- Information department, Intellectual Property, and Legal Affairs department
- Executive Center for Corporate Sustainability - Corporate Governance Taskforce



Resources invested

- The input of human resources and related information equipment of the responsible department.
- Entrust a qualified information management professional to be responsible for cybersecurity risk control.



Goals and targets

2021 Short-term Goals

1. Formulate information team and Cybersecurity Management Committee.
2. Complete internal cybersecurity and data privacy protection policies.
3. Complete cybersecurity policy promotion, education and training, and audits and reviews. The Company regularly promotes, establishes the employees' cybersecurity awareness, and organizes training.
4. Conduct regular cybersecurity external inspection annually.
5. Conduct regular in-house cybersecurity social exercises annually.
6. Complete the enhanced document management mechanism.

2022~2024 Mid-term Goals

- Complete the management of information-focused equipment retirement.
- Complete the expansion of the private cloud virtual structure.
- Complete the expansion of annual system disaster drill coverage.

2025 Long-term Goals

- Adopt ISO 27001 Information Security Management System in 2025.



Mechanisms for evaluating the effectiveness of the management approach

Evaluation of Management mechanisms

- Internal audit feedback
- Weakness test and infiltration test report.
- If the system is validated through the implementation of the project, it is based on whether it can pass FDA certification.
- If there are complaints regarding customer privacy impairment.

2020 Evaluation Results

- Internal audit feedback: No deficiencies.
- No complaints regarding customer privacy impairment.

Future plans for cybersecurity

In response to the growth of the Group's global commercial operations and the increasing demand for international data flow, the Group's headquarter has been gradually planning to establish its information operation team and is expected to establish an "Cybersecurity Management Committee" in 2021, as well as internal cybersecurity and privacy policies. In the future, the information unit will continue to implement the following three cybersecurity advocacy and to hold 1~2 employee training every year, and collect employee feedback to ensure that the Company's employees are aware of their responsibility for cybersecurity management.

Implementation of the protection of personal privacy

Employees should abide by laws and regulations and various cybersecurity norms.

Employees have the obligation to participate in various cybersecurity promotion and education sessions.

When employees shall discover a cybersecurity breach, they should report such matters as soon as possible and assist in handling them.

PharmaEssentia's privacy policy focuses on collecting and further processing private information from patients, health care professionals, personnel, and other individuals with whom the Company does business, and all employees must comply with this policy. The protection of privacy is mainly divided into the human clinical trial stage and the drug launching stage, both of which must comply with relevant internal regulations and national regulations to improve our responsibility for protecting personal information

Clinical trial stage



- PharmaEssentia entrusts qualified CROs to conduct human clinical trials and ensures that the CROs adopt strict confidentiality measures to collect, process, and utilize subject data.
- The Company also complies with the General Data Protection Regulation (GDPR), GCP, "Declaration of Helsinki," and relevant laws and regulations of various countries, such as Taiwan "Human Research Ethics Policy Guidelines" and "Medical Care Act" of Taiwan.
- The principal investigator of the trial plan must keep confidential the results of the examinee's examination and the physician's diagnosis and replace the subjects' names with numbers. Clinical trial hospitals shall also require relevant researchers to participate in clinical trials. The Company has no way to identify the subjects' personal information and has no access to other personal information.

Drug launching stage



- Post-Marketing Surveillance Study, PMS study: Before obtaining patient information, we will provide a patient consent form to ensure that we have the patient's consent and explain to the patient how we handle the information and protect the patient's privacy.
- To ensure that pharmacists in medical institutions, community pharmacies, and other healthcare units incorporate the concept of privacy protection in their daily routine when providing pharmacy services to the general public and healthcare providers, and actively protect and ensure that patients' privacy rights are not violated.

2-6

Comprehensive management of intellectual property rights

Materiality Topic

Management approach on intellectual property right

PharmaEssentia has been known for its high level of research and development energy since its establishment. The Company applies at the right time, in the correct country, for different types of invention patents for global technology deployment concerning the R&D progress of each project. Patent applications for inventions do not include patents on substances (including patents on chemical molecules and pharmaceutical dosage forms) and patents on methods/applications (including patents on new drug indications, patents on manufacturing processes, patents on treatment methods, etc.). With the above types of invention patents, a comprehensive intellectual property management system, and a complete intellectual property layout, PharmaEssentia can become a full-fledged international pharmaceutical company.

GRI 103-2

GRI 103-3



Policies

Internal Policy

- The management of the Company's intellectual property rights (including patents, trademarks, copyrights, and trade secrets) embodies three major aspects: acquisition, management, and application.
- Closely follow the regulations for the R&D cycle and complementing the Operational Procedures for Acquisition and Disposal of Assets to protect the Company's R&D personnel's intellectual property from infringement and not infringe the intellectual property rights of others.
- Intellectual Property Rights Management and Utilization Regulations.

External Compliance

- Patent Act
- Trademark Act
- Copyright Act
- Trade Secret Act
- Fair Trade Act



Commitments

The Company commits to following the rules for the management and use of intellectual property rights established by the Company to ensure that the academic achievement of the Company's R&D staff can become the Company's intellectual property and that the Company's intellectual property can be widely applied for and registered internationally so that more people in need can know about and have access to the new drugs, and that the intellectual property rights of others will not be infringed.



Responsibilities

- Intellectual Property and Legal Affairs Department
- Executive Center for Corporate Sustainability - Corporate Governance Taskforce



Resources invested

To accurately review the quality of the Company's intellectual property and to introduce projects related to intellectual property life cycle management, the Company invested nearly NT\$20 million in intellectual property-related expenditures in 2020. In addition to deploying considerable manpower to ensure intellectual property rights in the growth of more than 100 items to implement the maintenance and management of the Company correctly, internationally renowned experts in the field of pharmaceutical intellectual property are specially appointed to conduct in-depth evaluation, analysis, and suggestions on the company's intellectual property.



Goals and targets

2021 Short-term Goals

1. Complete the revision of the Intellectual Property Rights Management and Utilization Regulations to include a patent application for product life cycle management, risk control of intellectual property rights, and the new drug introduction policy of intellectual property rights.
2. Implement a policy to promote more aggressive global patenting of new drugs. For example, in addition to applying for patents in significant economies worldwide, the need to include low and medium development countries must be evaluated on a case-by-case basis for ongoing applications and new inventions on a rolling basis.
3. To extend the patent period, to swear the patent new drugs, and even to obtain better drug prices, the Company will consider applying for the corresponding patent registration system in each country immediately when obtaining the drug licenses in each country, to prevent the early infringement of generic drugs and counterfeit drugs by the pharmaceutical companies, and to achieve the purpose of supplying high-quality patented new medicines in the local area by the original factory only.

2022~2024 Mid-term Goals

1. The customized annual plan for intellectual property management, which is submitted to the Board of Directors at the beginning of each year, is evaluated at the end of the year and is aimed to be achieved or met for five consecutive years.
2. According to the new drugs/new dosage forms included in the life cycle management of the intellectual property rights management and utilization method each year, and the progress of the R&D team in developing new indications and new processes for old drugs, the current (annual) patent application plan is updated and reviewed at the end of the period to see if it is in line with the initial plan. It should produce new inventions continuously for five years and select outstanding innovations for global patent application.

2025 Long-term Goals

- Propose to submit the Company's intellectual property management system to the Taiwan Intellectual Property Management System (TIPS) validation project. Each year, the Company proposes a percentage of its global turnover for the previous year as the total budget for each year to advance the Group's intellectual property management (recognition/validation) program. At the beginning of the period, the intellectual property department prepares a plan based on the total budget obtained for the year, commensurate deliverables to drive the project, and reviews. It revises it at the end of each period.



Mechanisms for evaluating the effectiveness of the management approach

Evaluation of Management mechanisms

Internal audit mechanisms:

- Procedures for the Management and Application of Intellectual Property Rights.
- Property Management Regulations
- Contract Management and Review Regulations
- R&D cycle rules - R&D information and document control operations (such as laptop document management)
- Procedures for Acquisition or Disposal of Assets
- Code of Ethical Conduct (e.g., company confidentiality rules), confidentiality provisions in employee employment contracts

External audit mechanisms:

- FSC's Corporate Governance 3.0 Sustainable Development Blueprint Evaluation Indicators: submit and report the "Intellectual Property Management Plan Linked to Operational Objectives" to the Board of Directors at least once a year.

2020 Evaluation Results

- Patent: as of 2020, the Company had 74 valid patents worldwide.
- Trademark: as of the end of 2020, the number of valid trademark registration certificates was 71, and 12 certificates were issued in 2020.
- Regularly report to the Board of Directors' meeting on the intellectual property management system and implement the Group's intellectual property rights on an annual basis starting in 2020.

Patents and trademarks highlights

74

Number of accumulated valid patent rights certifications obtained

78 countries

Valid patents certifications are distributed in 78 countries around the world

71

Number of registered trademarks

29 countries

Registered trademarks are distributed in 29 countries around the world

The number of valid patents granted is 74 worldwide, regarding trademarks, 71 registered trademarks issued by various countries in 2020, and 12 new ones. The legal and intellectual property department annually reported to the Board of Directors on the management plan of intellectual property rights linked to operational objectives since 2020. In 2018, the Company was about to obtain drug license in many countries for 百斯瑞明®/ BESREMI® ahead of schedule, expanding the intellectual property rights to a global scale.

Chapter 3

Product Quality and Patient Safety

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Chapter 3

Product Quality and Patient Safety



Relevant material topics



Product quality and safety management



Patient safety



Stable and secure supply chain

Relevant stakeholders



Suppliers/contractors



Government agencies



Patients



Strategic partners

Summary of Chapter 3

Highlights of 2020

One of the main objectives of PharmaEssentia is to promote healthy human rights and operations by ensuring the timely delivery of high-quality, safe drugs to patients. Our management approach on the drug supply chain ensures that the drug supply meets the needs of our patients. Our management objective is to require that the right amount of safe and effective drugs are consistently available to patients at the right time and place, with appropriate cost management for the benefit of our shareholders. In addition, ensure that the entire supply chain must comply with external regulations and a strict internal quality system, including from upstream raw material suppliers, outsourced manufacturing or distribution partners to downstream customers and users. It is regularly reviewed and evaluated for performance to reduce risk and to improve management continuously. The Company completes the coordination of supply and demand, as well as risk management in the global supply chain by integrating forecasting for clinical and commercial demand, inventory management, raw material procurement, production scheduling, production, release, storage, serial number management, and mechanisms for report and recall. In terms of raw material procurement and supplier management, we regularly evaluate internal and external factors that may affect the timing

or quantity of drug supply and take necessary measures. For example, the risk of material and chain breakage is reduced by establishing safe stock level and alternative material sources. We have found a legal and sound global distribution management mechanism following PIC/S GDP regulations to ensure that the quality or integrity of the drug will not be adversely affected from the time it leaves the factory to the time it is used, regardless of the environment and activities. After the products launched, the drug safety monitoring mechanism and the “Pharmacovigilance function” team at our headquarter coordinate and monitor the information reported by our subsidiaries and CROs to protect patients’ drug use safety jointly.

Meanwhile, we have established a global real-time notification mechanism and an adverse drug reaction (ADR) notification mailbox and commissioned CROs to set up a global ADR notification mailbox. In addition, we have established a comprehensive procedure of recall and traceability management to keep a complete record of the flow and use of drugs. When the quality of a product is in doubt, a drug recall mechanism can be completed quickly and effectively, providing patients with additional protection for drug safety.

Performance highlights

4,000+

Comprehensive quality and safety management, standard operating procedures, and various plans and reports.

Officially established Pharmacovigilance function Team

Completed the establishment of a global real-time notification mechanism and adverse reaction notification mailbox.

78,465 training hours 2,399 participants

GMP-related training statistics.

U.S. filling factory passed FDA inspection.

Completed and submitted the first BESREMI[®] Periodic Safety Update Report (PSUR).

No post-marketing severe adverse reactions in 2020.

100% for 2 consecutive years

For two consecutive years, all the suppliers/contractors required to sign quality agreements, internal assessments, and on-site audits are completed.

Top 3 sustainability management priorities for suppliers

Three major supply chain management priorities were completed in 2020, and the promotion and signing of the "Supplier Code of Conduct" are expected to take place in 2021.

Built a stable and secure global supply chain.



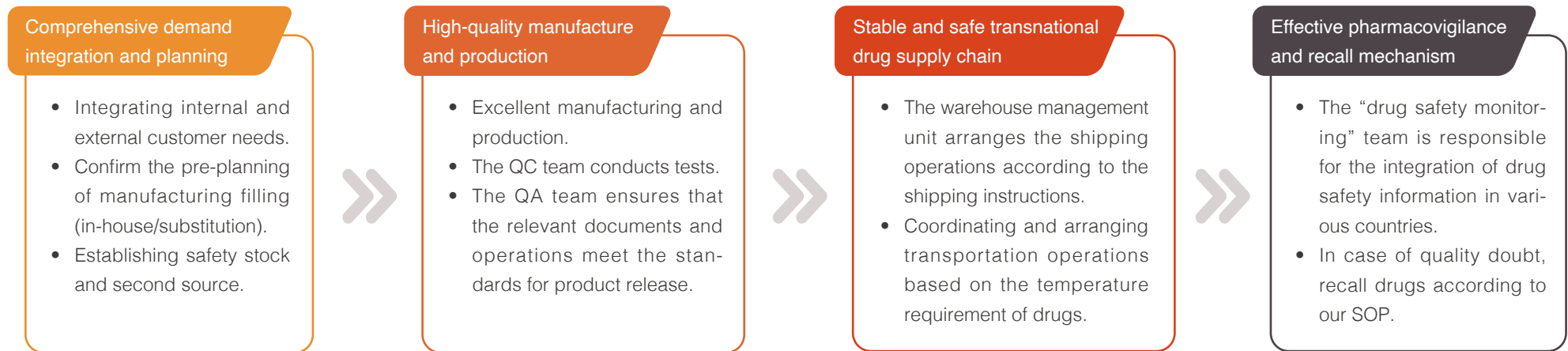
3-1

Constructing a comprehensive supply chain system

Materiality Topic

SASB HC-BP-260a.1

Many global patients with rare diseases highly rely on pharmaceutical companies for a continuous supply of safe and reliable medicines to sustain their lives and quality of life. Therefore, establishing a comprehensive, stable, secure, and high-quality pharmaceutical production and multinational supply chain is a mission that cannot be ignored by all PharmaEssentia's employees and upstream and downstream supply chain partners.



Comprehensive demand integration and planning

We integrate clinically market needs through inter-departmental production and sales coordination meetings on an as-needed basis and confirm the production schedule with the supply side and the production side to ensure an impeccable value chain.

Accountable procurement and supplier management

In the procurement of raw materials, we strictly control the selection, evaluation, and approval of suppliers of raw materials, materials, and instruments/equipment through rigorous procedures and use local manufacturers as our priority partners. To ensure a stable supply, we actively establish a safe stock level and timely keep track of raw material delivery dates. In addition, we are also actively establishing alternative material sources to reduce the risk of raw material shortage and ensure a stable supply of high-quality products. In 2020, PharmaEssentia set three major supplier management priorities: Communicating our sustainability philosophy and practices to our procurement partners, improving our management and response capabilities, and establishing alternative material sources. Therefore, we can work together to establish a stable procurement supply and protect patients' rights to medicine.

High-quality manufacture and production

PharmaEssentia carries out its manufacture and delivery procedures in compliance with regulations, including current GMP, ICH, EMA, FDA, and more than 4,000 internal standard operating procedures. The production equipment in the Taichung plant is selected from major European and US brands. We produce high-quality drugs with high equipment standards, the most advanced technology, meticulous production procedures, and cleaning management. The QA and QC departments of the quality system control the products strictly to provide high-quality and safe drugs for patients.

Drug preservation and transnational delivery

In terms of product distribution, PharmaEssentia strictly controls the packing process and transportation process to ensure that the products are stored within the temperature range of 2°C to 8°C. Besides, we also provide the maintenance of the cold storage equipment so that all procedures align with the GDP requirements necessary to transport the product. In terms of global layout and supply and sales, we out-licensed the strategic partner AOP Orphan for development and marketing in the European region, and we also established local cooperation with contracted filling and transportation companies. In the United States, the US subsidiary organized its marketing team and commissioned the local filling agent Pyramid Laboratories Inc, a US filling plant, has successfully passed the FDA inspection in early 2021. In Taiwan, our local sales and logistics team is responsible for the medicines' supply and marketing. Pyramid Laboratories Inc., Taiwan manufacturers, are also expected to be inspected by the U.S. FDA in Taiwan as soon as the pandemic eases.



Effective pharmacovigilance and recall mechanism

Pharmacovigilance refers to the safety monitoring mechanism for large-scale and widespread use of the drug after it is marketed to ensure the safety of patients' medication. At present, the Company has entrusted contract research organizations (CROs) with establishing a pharmacovigilance mechanism. The headquarter has established a pharmacovigilance taskforce, responsible for integrating the clinical trial information of all subsidiaries, building a safety database to integrate drug safety-related information, and preparing and providing safety reports required by regulatory agencies. In addition, the Company has established a product number-tracking management system and a drug recall policy to ensure product quality. Then when a product quality problem occurs, the product can be recalled, the related inventory can be disposed of within the time limit regulated by the competent authorities, therefore reduce the risk of illegal infiltration of counterfeit, banned, or substandard drugs into the supply chain.

Management approach on stable and safe supply chain

Materiality Topic

With the issuance of marketing authorization approval in various countries, PharmaEssentia's products have begun to enter the markets of many countries. Therefore, the critical task at this stage is to establish a safe and stable global supply chain and transportation/distribution management mechanism to ensure drug quality from the Taichung plant to the patients in various countries before use. Following the PIC/S GDP, PharmaEssentia has established a legal and comprehensive global distribution management mechanism and has established different internal policies and operational guidelines to ensure the compliance of operational processes and the accuracy and completeness of record information. In this way, we guaranteed the drug safety of every patient around the world.

GRI 103-2

GRI 103-3



Policies

Internal Policy

- Quality management policy
- Risk management policy
- Raw material management policy
- Storage and distribution policy
- Outsourced activities policy
- Product packaging and identification policy

External Compliance

- WHO Good Storage and Distribution Practices for Medical Products
- Strictly comply with legal and external GxP regulations for all phases of the product cycle, from development and production to sales.



Commitments

PharmaEssentia is committed to building a stable, safe, and high-quality drug supply chain and is committed to improving the accessibility, affordability, and availability of pharmaceutical products and continuously enhancing the safety and stability of the overall supply chain.



Responsibilities

- Group headquarters SCM includes business units, procurement units, production management units, logistics units, production and manufacturing units, QA units, and SCM units.
- Executive Center for Corporate Sustainability - Product Quality and Patient Safety Taskforce



Resources invested

Personnel / operational input:

- Human resources (including training), ERP enterprise resource planning information

Expense input:

- Raw materials, delivery materials, and transportation costs



Goals and targets

2021 short-term goal

1. Meet the needs of drug users immediately.
2. Global economic activity continues to be impacted by the COVID-19 pandemic in 2021. All business units covered by the supply chain have adopted feasible strategies to reduce the risk of supply chain disruptions, building on the experience gained in 2020.

2022~2024 mid-term goal

1. Enhance customer satisfaction and plan for potential market demand by improving delivery reliability and flexibility.
2. The global economy is expected to recover as the COVID-19 vaccines become more widely available gradually. After meeting the needs of the drug for users, the further step is to improve the satisfaction of drug users. From the supply chain team's point of view, this level of satisfaction goes beyond quality issues. It includes delight in business activities, creating maximum benefits for both the Group and the patients.
3. As the Company continues to obtain drug licenses in different countries, planning and preparing for immediate and stable supply to potential markets will be an essential mid-term goal for the supply chain team.

2025 to the long-term goal

1. Optimize the internal process of the Group (e.g., value flow), and integrate the needs of various subsidiaries/countries, and reasonably control and allocate necessary resources.
2. The competent authorities of various countries have formulated strict laws and regulations to regulate the inspection specifications, packaging labeling, and shelf life of drugs. The supply chain team is also committed to integrating these requirements to use resources within the Group efficiently.



Mechanisms for evaluating the effectiveness of the management approach

Management Assessment Mechanism

- "Standard Operating Procedures for Supplier Management " and " Procedure for Supplier Management "
- "SOP for Purchasing Management " and "Procedure for Supplier Audit"
- "Corporate Social Responsibility Best Practice Principles"
- Drug safety notification system of competent authorities in various countries
- Drug supply shortage notification system of competent authorities in multiple countries
- Drug complaint system established by PharmaEssentia
- Regular management meetings of PharmaEssentia and product quality review

2020 Assessment Results

- After obtaining the drug license for 百斯瑞明® in Taiwan in June 2020, the Company had continued to provide stable supply to patients.
- In addition to sales, the Company also cooperates with medical institutions to provide patients with free medical care in compassionate use.
- The number of medication discomfort, adverse events, or complaints from the hospitals and patients reported in 2020 was 0.
- We have established sufficient stock inventory according to the number of drug users.
- The number of cases of product failure or safety concerns due to transportation and storage activities in 2020 was 0.

3-2

Accountable Supplier Management

Three key points to strengthen supplier sustainability management

The impact of the COVID-19 pandemic in 2020 on the upstream supply chain of global companies is still spreading around the world. The pandemic strengthens PharmaEssentia's belief in working with its supplier partners for mutual benefit and prosperity. We believe that the only way to create long-term and stable value for the industry and patients is to spread the concept of sustainability and to work together with suppliers/contractors. In 2020, PharmaEssentia set three major supplier management priorities to ensure a stable procurement supply with its supply partners and protect patients' rights to medicines.

Sustainability declaration: Suppliers / contractors co-prosperity

As the benchmark of sustainability in the industry, PharmaEssentia has taken the lead in social responsibility, sustainable management, and giving back to Taiwan. Through formal and informal declarations of sustainability, we hope to convey this concept to our supply partners and invite them to join us to create a positive and long-term impact. We expect to promote the "Code of Conduct for Suppliers" in the first half of 2021 and sign the "Code of Conduct for Suppliers" in the second half of the year.



Sustainability Proclamation

To work with our supplier partners for mutual benefit and prosperity, our plan is:

- Declaration: To convey the corporate sustainability philosophy and practices of PharmaEssentia.
- Action 1: Promote the "Code of Conduct for Suppliers."
- Action 2: Sign the "Code of Conduct for Suppliers."



Improved Management

In the face of a changing world, our strategy to enhance our management and response capabilities is:

- Information mastery.
- Enhance supplier management capabilities.
- Strengthen the interaction with suppliers.



Building Substitutional Resources

In order to ensure stable supply, our approach is:

- Identify critical material.
- Screen out candidate raw materials.
- Quality confirmation, experimental confirmation.
- Manufacturing trial mass production
- QA monitoring and regulatory compliance.



Supply chain management and reaction enhancement

Sustainability declaration

“ *PharmaEssentia has been upholding the original intention all along the way.*

As we grow and thrive, we hope that every member of the biotech industry chain, including every supplier partner, will grow together with us, work together for the good, and value corporate social responsibility together.

We value employee rights and safety, care for the global environment, and operate with sustainability and integrity. We also hope to share this philosophy with our supply partners and work together with them to put it into practice. **”**

The world experienced an unprecedented disaster of COVID-19 in 2020, with economic activity and factories shutting down in most countries, leading to climbing unemployment rates and recessionary scenarios. Under the impact of COVID-19 pandemic, the supply chain was also affected, and there was a shortage of materials in factories and a higher percentage of delayed shipments, leading the price fluctuations and increases. However, the influence factors to prepare sufficient materials, such as cost and validity must be considered simultaneously. Therefore, achieving a balance between maintaining low inventory and long-term material preparation and rapid response is a vital part of improving the supply chain management capability of PharmaEssentia. In this regard, we will work in the following directions:

- 1 Timely grasp of factors that may affect the supply chain (disease, climate change, natural disasters, etc.).
- 2 Enhance supplier management capabilities.
- 3 Strengthen the contact and interaction with suppliers, grasp the changes of suppliers in real time, and continuously monitor the information related to material delivery to ensure the overall information of transportation and logistics in a timely manner.
- 4 Update the lead time of raw material procurement from suppliers.
- 5 Enhance safety stocks and monitor changes in demand at customer front-end medical facilities and patients.
- 6 Investigating the situation of pandemic in the countries producing raw materials, and evaluating the risk and possibility of material breakage.
- 7 Actively establishing a second source of raw materials to reduce the risk of supply chain disruption.

Establishment of alternative sources

Pharmaceutical manufacturing is subject to strict regulations and supervision in various countries. Therefore, once faced with a shortage of raw materials, abnormal quality, or transportation delays, it is often impossible to immediately replace them. It also affects the supply schedule of biotech, pharmaceutical companies and may even result in patients not obtaining drugs in time, causing life and health hazards. Therefore, one of the key points of PharmaEssentia's supplier management is to establish a second source in advance to enhance the stability of the material source. In this regard, we have conducted a comprehensive survey of raw materials and determined the priority of materials to be introduced into alternative sources following our internal standard operating procedures. For materials with immediate risk of material breakage, we have established alternative material sources. For materials with the potential risk of material breakage, we will first upgrade the safety stock to reduce the risk of material breakage. PharmaEssentia carries out the establishment of alternative sources of material through the following procedures:



Review of raw materials that need to be established as an alternative source, the basis for judgment is:

- The manufacturer informed that the production is about to be suspended.
- Compliance requirements.
- Conduct material risk assessment and evaluate the material criticality according to the procedure of "Material Criticality Assessment."



Performance quality confirmation.



The process development is verified by the process development experiment and the trial production is carried out. The tested raw materials will then enter the GMP control procedures (e.g. supplier evaluation, specification inspection and method establishment, etc.), and after completing the relevant procedures, they will enter the reserve list.



All test data and documentation are continuously monitored by QA at each stage of alternative source development to ensure that the overall process is fully compliant with regulatory standards.

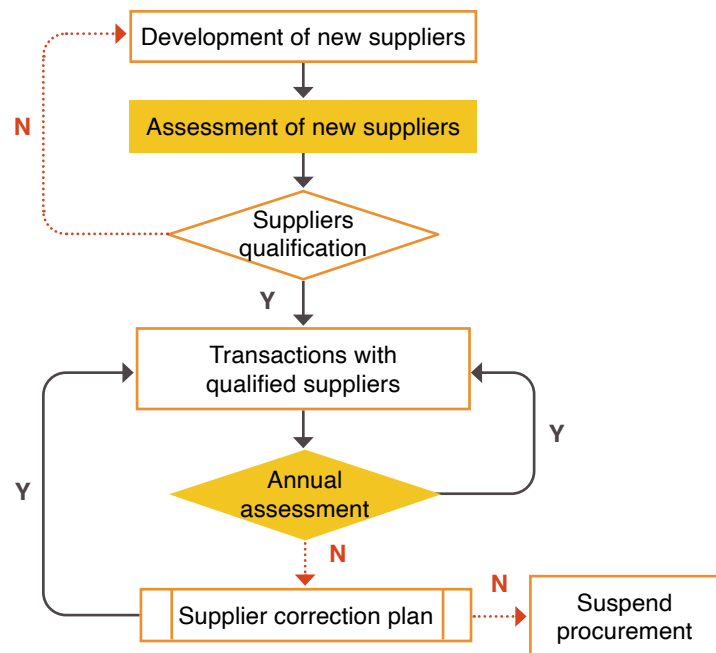
Management process of supplier/contractor

GRI 102-9

GRI 204-1

SASB HC-BP-430a.1

To ensure that our suppliers and the raw materials and equipment they supply meet PharmaEssentia's quality, delivery requirements, and GMP regulations, we strictly control the selection, evaluation, and approval of suppliers of raw materials, materials, and equipment through a rigorous process. QA department of PharmaEssentia formulated the "Standard Operating Procedure for Supplier Management" and "Procedure for Supplier Management" as the approval procedures and operation guidelines. Raw materials can only be procured from suppliers approved by the QA department. Furthermore, the Company requires suppliers to sign a "Quality Agreement," which sets out the Company's rights and responsibilities for quality and technology-related issues to ensure that both parties agree on products and quality requirements. In 2020, all suppliers that are required to sign the Quality Agreement had signed the agreement. When looking for suppliers/contractors, we prioritize the cooperation with local suppliers and increase the number of local companies and local spending.



Procurement expenditure statistics in 2019 and 2020				
Types of procurement	Percentage of procurement activity from local suppliers		Percentage of procurement activity from non-local suppliers	
	2019	2020	2019	2020
Ingredients	88.0%	82.8%	12.0%	17.2%
Materials	41.0%	99.3%	59.0%	0.7%
Consumables	99.6%	100.0%	0.4%	0.0%
Reagents	99.0%	99.8%	1.0%	0.2%
Instruments/equipment	99.8%	100.0%	0.2%	0.0%
Contracted services / manufacture	37.0%	14.9%	63.0%	85.1%
Engineering construction	90.0%	100.0%	10.0%	0.0%
Drugs	0.0%	100.0%	0.0%	0.0%
Total	67.0%	75.3%	33.0%	24.7%

Figure 8: Procedure of supplier management

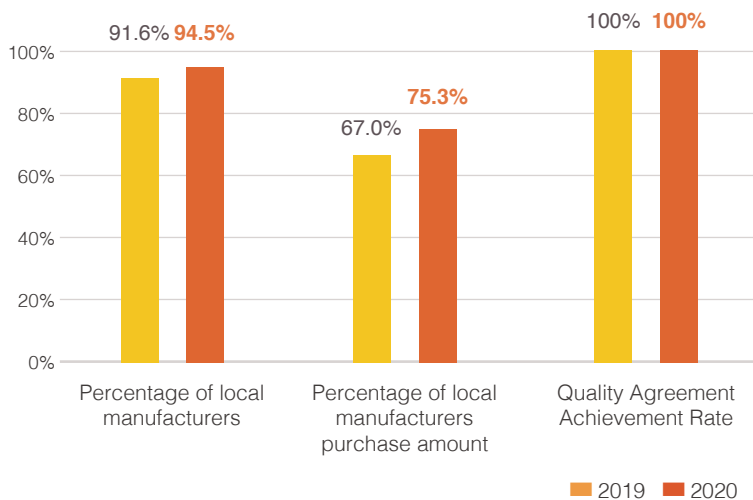
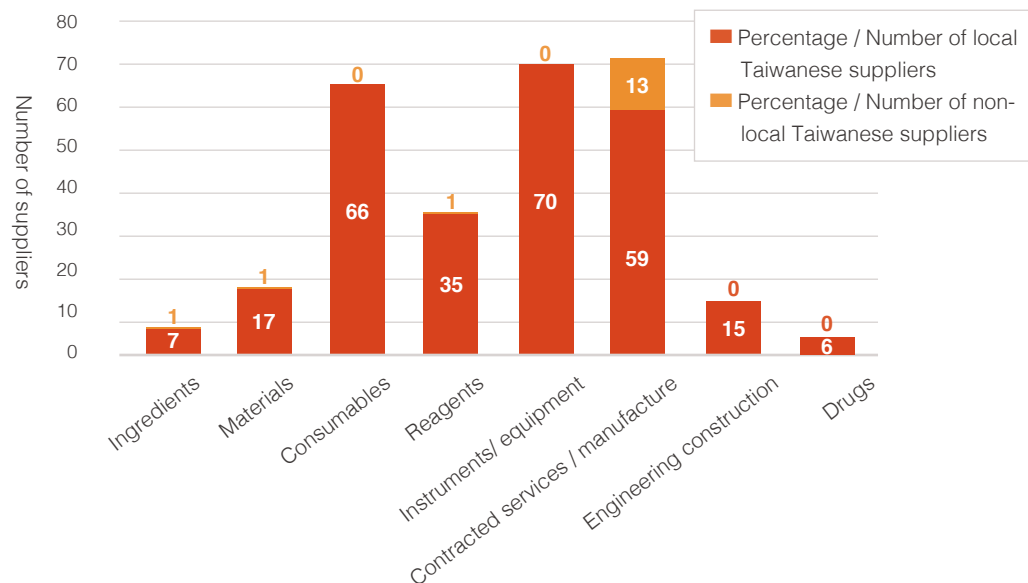


Chart of 2020 procurement from suppliers / contractors



Management strategy of supplier/contractor

To improve the efficiency of supplier management, PharmaEssentia classifies the purchased materials or services into four categories, including "Strategic materials," "Critical materials," "Leveraged materials," and "General materials," based on the risk and purchase amount. Then different management strategies are drawn up according to the market characteristics and product attributes of each type of material or service.

Category of procured material

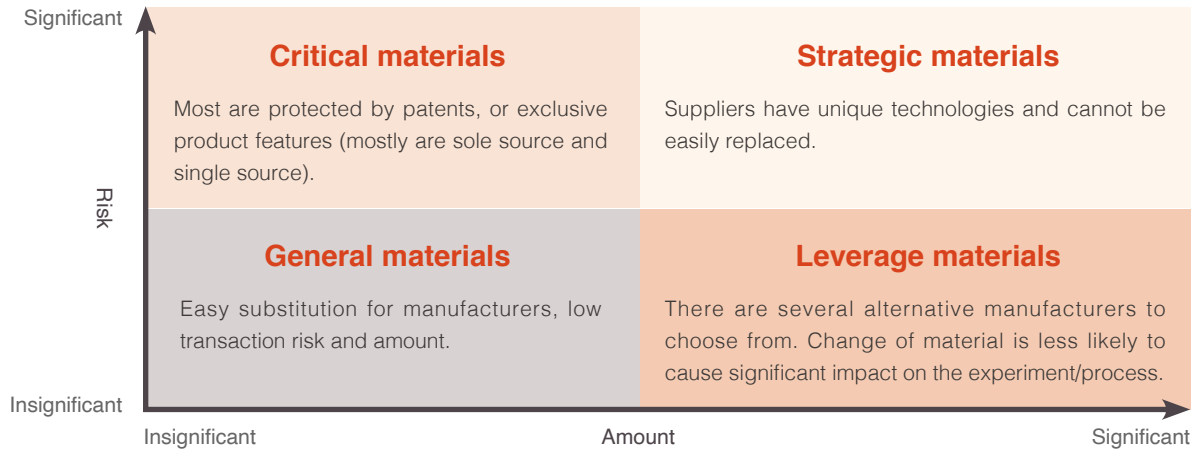
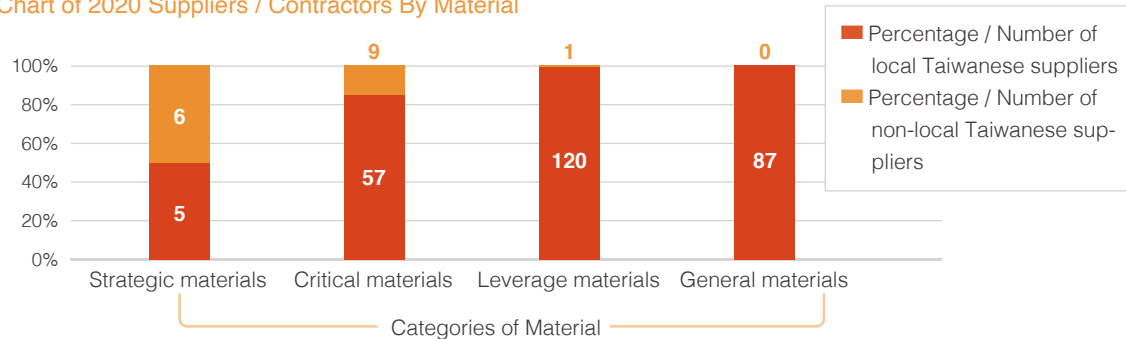


Chart of 2020 Suppliers / Contractors By Material



Supply management strategy

Strategic materials

1. Strategic alliance: Substantially strengthening the alliance with suppliers, mutual benefit and mutual prosperity.
2. Maintaining good interaction with suppliers and establish good cooperative relations.
3. Evaluating the Total Cost of Ownership (TCO): including performances such as service scope, quality and timeline.
4. The signing of the contract ensures the service quality and content.
5. Self-manufacture and self-production.

Critical materials

1. Ensuring the stability of the source of supply.
2. Maintaining good interaction with suppliers and make good use of service information provided by suppliers.
3. Looking for new suppliers and second source.

Leverage materials

1. For routine materials, suppliers are requested to prepare inventory for timely delivery.
2. Integrating procurement items and the needs of various departments.
3. Price and cost control, active price inquiry and comparison.

General materials

1. Carrying out routine procurement, following and maintaining the required procurement procedures.
2. Centralizing order quantity and frequency.

Selection and assessment of new suppliers/contractors

96.2%

Among the 26 new suppliers, there are 25 local suppliers, accounting for 96.2% of all suppliers.

The selection and assessment of new suppliers/contractors are based on 3 major indicators: quality system, technical skills, service, and support capabilities. According to the "Standard Operating Procedure of Procurement Management" before initial procurement, potential new suppliers/contractors who intend to have business dealings with the Company need to be evaluated by the relevant user departments, QA department, and procurement unit according to the "Standard Operating Procedure of Procurement Management" before initial procurement. In 2020, there were 26 new suppliers, and 25 of them are local suppliers, accounting for 96.2% of all suppliers.

3 major indicators for new suppliers / contractors



Annual assessment of suppliers/contractors

SASB HC-BP-430a.1

144

Suppliers under internal assessment in 2020

5

Suppliers underwent an on-site audit in 2020

**100% for
2 consecutive years**

Completed 100% of internal assessment for two consecutive years

**100% for
2 consecutive years**

100% completion of the on-site audits for two straight years

PharmaEssentia conducts supplier/contractor assessments annually to ensure the quality of suppliers' products and services. The assessment of suppliers is based on an internal assessment review and on-site audit. The internal assessment review is carried out by the relevant user department, warehouse management department, QA department, QC department, and procurement unit. The indicators of the internal assessment cover the quality of the products or services delivered by the suppliers, punctuality of delivery, document integrity, handling of abnormalities and service capabilities, and prices. The QA department carries out on-site audits, QC department, and manufacturing-related personnel following the "Procedure for Supplier Audit" to understand suppliers' manufacturing and quality control status on-site. If there is a high risk in the supplier, we will shorten the frequency of re-examination and take improvement actions.

If there are significant deficiencies, the procurement will be suspended immediately. Among the 11 suppliers to be audited on-site in 2020, 6 foreign suppliers were not audited on-site due to the impact of the COVID-19 travel ban issued by various countries. Documentary audits replaced adjustments during this period, and it is expected that on-site audits will be performed after the travel ban is lifted. The remaining 5 suppliers have completed on-site audits following the "Procedure for Supplier Audit." To conclude the audit results in 2020, 144 suppliers required to perform internal assessment and 5 suppliers needed to conduct on-site audits have all completed the evaluation and on-site audits. Therefore, all suppliers met our requirements, and there are no high-risk suppliers.

List of 2020 assessment of suppliers/contractors					
Types of procurement	Types of assessment	Internal assessment ^(Note1)		On-site audit ^(Note2)	
		Number of suppliers to be assessed	Actual number of suppliers assessed	Number of suppliers to be audited	Actual number of suppliers audited
Ingredients		4	4	1	-
Materials		10	10	2	1
Consumables		26	26	-	-
Reagents		12	12	-	-
Instruments / equipment		41	41	-	-
Contracted services / manufacture		45	45	8	4
Engineering construction		6	6	-	-
Drugs		-	-	-	-
Total		144	144	11	5

Note 1. Suppliers assessed are those who have business dealings with the Company from July 1, 2019, to June 30, 2020. If the supplier reached Level A or B in the internal assessment in the previous year, it might be exempted from the evaluation for the current year.

Note 2. Due to the impact of the travel ban of COVID-19, a total of 6 foreign suppliers could not be audited on-site in 2020, so the audit was adjusted to document audit.

Note 3. The assessment for suppliers/contractors of Panco Healthcare Co., LTD. (hereinafter referred to as Panco Healthcare), a subsidiary in Taiwan, will be conducted following the regulations of the headquarter from 2021 and therefore is not included in the above table.

3-3

Ensuring the quality and safety of drugs

Materiality Topic

Management approach on product quality and safety management

For the value chain of PharmaEssentia, from R&D, clinical trials, commercial mass production to patients' use, we use standardized operating procedures, comprehensive quality management, and complete product traceability systems to ensure safety, effectiveness, and high quality of the drugs used by patients.

GRI 103-2

GRI 103-3



Policies

Internal Policy

- There are about 20 internal quality management policies that comply with international standards, such as the "Quality Management Policy," "Raw Material Management Policy," "Production and In-Process Control Policy," and "Quality Assurance Policy."
- "Complaint and Recall Policy," etc.

External Compliance

- Complying with international standards: ICH, GLP, GCP, EudraLex Volume 4 Good Manufacturing Practice (GMP), 21 CFR 210/211/600 (Code of Federal Regulations), GDP, GVP.
- Complying with regulations formulated by competent local authorities. For example, "European Pharmacopoeia," "United States Pharmacopeia," regulations developed by FDA, "Medical Care Act," and "Pharmaceutical Affairs Act" of Taiwan.



Commitments

- The concept of "Patients Safety and Quality First" is deeply rooted in each staff's daily operation and life so that they will prioritize quality and safety.
- Ensuring drug risk management and protect the safety of patients' use of drugs.



Responsibilities

- QA department, QC department, clinical trial QA, Pharmacovigilance function.
- Executive Center for Corporate Sustainability - Product Quality and Patient Safety Taskforce



Resources invested

Personnel/operational input

- Dedicated department for quality maintenance, such as QA, QC, Pharmacovigilance function, etc.
- A pharmaceutical regulations department is established to track international pharmaceutical regulatory trends and norms and provide advice and consultation on regulations from various departments.
- Introduced electronic quality system in 2020.

Expense input

- Invested about NT\$90 million in quality maintenance in 2020.



Goals and targets

2021 short-term goal

1. Passed US FDA PLI (Pre-License Inspection) pre-approval inspection and obtained certification in 2021.
2. Complete the import of electronic documents and quality systems (including document system, education, training system, QMS system, etc.).
3. Continuously strengthen GMP-related training to implement quality operations and management, such as introducing a Training Management System to ensure 100% implementation of the training plan set at the beginning of each year.
4. Establish a Clinical Quality Assurance unit responsible for quality assurance and audit activities related to clinical trials and drug safety monitoring so that personnel can be familiar with and integrated into product safety practices.

2022~2024 mid-term goal

1. Pass the regular drug good practice inspections for every 2~3 years performed by the EMA, TFDA, and FDA. The estimated checking time is in the following order:
 - 2021: TFDA, FDA
 - 2022: EMA
2. Continue to optimize and improve the quality system (including inviting domestic and foreign experts to review and optimize existing systems, such as optimizing abnormal incident handling and investigation systems) and updating the system to meet the existing regulations.
3. Pass PMDA inspection.

2025 to the long-term goal

- Pass the regular inspection by the competent authority of the country that has obtained the marketing authorization approval.



Mechanisms for evaluating the effectiveness of the management approach

Management Assessment Mechanism

- Passed the regular drug good practice inspections performed by the FDA, EMA, and TFDA.
- Each internal department shall undergo internal quality audit at least once a year.
- According to demand, foreign experts are invited to conduct quality audits when necessary.
- A third-party entity regularly audits clinical trials in addition to the inspection by the competent health authorities.
- Established Data and Safety Monitoring Board (DSMB) to perform audits and assessments.

2020 Assessment Results

- The whole plant passed TFDA's GMP and GDP inspection.
- In early 2021, the aseptic agent filling plant passed the MFDS GMP audit certification in South Korea.
- No critical violations of relevant drug good practices and regulations occurred.
- Internal quality audit results: Each department received internal quality audits at least once a year. 12 internal audits were conducted in 2020, and 47 deficiencies were found, including 7 major and 40 minor deficiencies, with an improvement rate of 91% as of March 31, 2021.
- A total of 5 consultants were invited to conduct the GMP systematic inspection in the factory as the pre-inspection, and 381 improvement suggestions were made, 100% of which were improved by March 31, 2021.
- No incident related to product quality must be reported.
- Underwent on-site audit by the Institutional Review Board of the experiment hospital, and no major violation of laws and regulations were found.

Comprehensive quality and safety management and standard operating procedures

The Taichung manufacturing plant of PharmaEssentia has a detailed organization and operation chart. It is equipped with sufficient and experienced qualified personnel. The QA and QC departments of the quality system are responsible for the management and supervision of process quality and safety. The Company has the internal "Quality Manual" and more than 4,000 related standard operating procedures and specifications, plans and reports to ensure the quality and safety of products.

4000+

Comprehensive quality related standard operating procedures and various plans and reports

Manufacturing quality maintenance

To ensure that the quality inspection of the environment, raw materials, intermediate products, drug substances and finished products of the PharmaEssentia's Taichung plant comply with GMP regulations. The Company has established the "Manufacturing and Process Control Procedures" to standardize process control, monitoring labeling, and inspection and control operations workflow. Before starting production, the production department needs to confirm that the process area meets the release conditions and is approved by the QA department before production can proceed. Products are also subject to batch record review and release by the QA department. The procedures for control operations in the process area are defined in the "Cross Contamination Prevention Management Procedures" to reduce the risk of cross-contamination.

Environmental quality monitoring

The Company's QC department is responsible for environmental monitoring and quality inspection of raw materials, process intermediates, drug substances, products, and equipment cleanliness of the production line. The Company formulated the "SOP for Monitoring Plan for Environment," "SOP for Water System Monitoring," and "Microbiological Identification and Statistics Standards," etc., to ensure effective monitoring of environmental microorganisms and timely appropriate response measures to reduce the risk of microbial contamination of products significantly. For the ecological quality monitoring results, we will conduct further trend analysis. The Company holds annual meetings and discussions about the analysis reports. If the relevant specifications need to be modified, they will be revised according to the change control procedures. The conclusion of the 2020 monitoring trend report on the production environment (air conditioning), water system, compressed air, and biosafety operation cabinet shows that the monitored systems used to support manufacturing can meet the original design requirements and comply with laws and regulations.



Figure 9: Monitoring personnel performs water system monitoring and sampling, using different pipe fittings according to other water quality sampling points.

Risk assessment management of quality safety

GRI 102-15

Effective quality risk management is an indispensable part of maintaining drug quality and safety. Quality risk management is a systematic process for evaluating, controlling, communicating, and reviewing quality risks. It must be implemented in the entire drug life cycle, including clinical trials, raw material manufacturing, procedures, operations and equipment, product transportation, and post-market drug safety monitoring. Only through well risk management can the safety of patients be guaranteed, and the risks of patients using drugs can be effectively controlled and reduced.

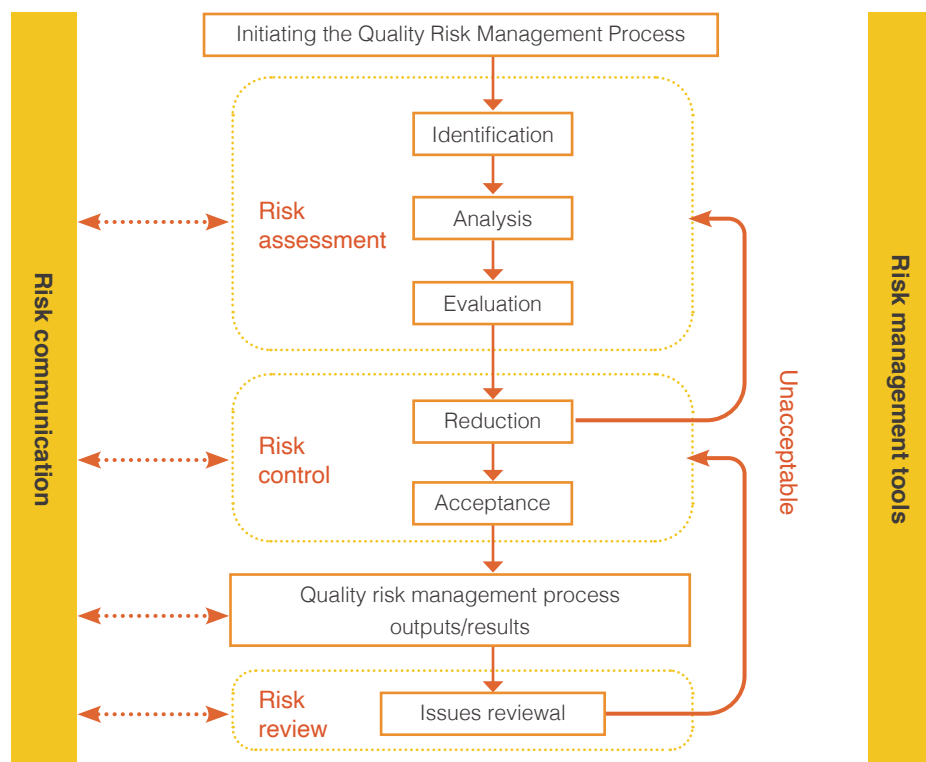


Figure 10: Flow chart for quality risk management

Clinical trial quality risk assessment and maintenance

CROs perform the risk assessment of clinical trials, and the Company implements quality assurance and quality management in clinical trials following internal operating procedures. In the future, it will be audited by the internal clinical trial QA staff.

Before Clinical Trial:

Assessing the degree of risk that may be encountered during the trial process according to the characteristics of the trial drug and the difference in the trial design.

According to the risk level, a case specific "Monitoring Plan" and "Audit Plan" are developed to perform QA and QC activities to ensure that the rights and welfare of the subjects are protected and that the clinical trial is conducted and the data generated, recorded and reported in compliance with the trial plan, GCP and related regulatory requirements.

QA Activities:

Include an independent audit system where problems identified are properly evaluated and tracked, and CAPA is developed.

QC Activities:

Include implementation monitoring and co-monitoring.

In addition, before implementing clinical trials, internal training and external host conference training will be held to provide researchers with training on product safety and leave written training records. During the clinical trial process, the safety information of the trial drug will be compiled in the "Investigator's Brochure (IB)." The manual needs to be regularly reviewed and updated in real-time every year, and the updated version is provided for reference by relevant experimenters.

Manufacturing quality risk management

For the risk management for the operation of the Taichung manufacturing plant, the risk level assessment is conducted based on the “Quality Risk Management Procedures” formulated under the ICH Q9 Quality Risk Management and the tools recommended by ICH Q9, and based on the “Probability,” “Severity” and “Detectability” of risk factors. The Company has formulated the “Equipment Risk Assessment Procedures” following the United States Pharmacopeia for instruments and equipment. It classifies risks based on the “impact on GMP” and “system complexity” to reduce the operation risk of damaging product quality. And the Company has introduced risk management to control the production process, environmental control, material supply, and other matters to minimize quality hazards.

In 2020, the Taichung manufacturing plant of PharmaEssentia held a total of 11 cross-departmental risk assessment team meetings and discussed the risk issues found in the plant during the meetings.

8 departments

Inter-departmental participation in procurement, supply chain, QA, QC, filling plant, construction, production, R&D, etc.

11

Risk assessment team meetings in 2020

74

Attendees were present at the risk assessment team meetings in 2020



Product quality assessment and continual improvement

To maintain the long-term stability of drug quality and safety, to be in line with GMP, and to maintain the effective quality management system, PharmaEssentia conducts regular internal audits and occasional external audits to review the effectiveness of the quality management system and GMP compliance. The Company has formulated the “Procedure for Product Quality Review.” It regularly performs product quality evaluation to ensure that the existing manufacturing process and the materials used can produce products that consistently meet the expected quality. A Product Quality Review meeting is held every quarter. Through the results, review and improve quality incidents, implement CAPA based on severe conditions to ensure the stability and uniformity of product manufacturing processes and product quality, to use this as a basis for process improvement and optimization. There were 48 quality system deviation events in 2020, including one critical, five major, and 42 minor deficiencies. Among them, relevant regulations have been formulated for essential incidents to prevent recurring incidents, and the improvement was completed in February 2020. As for other deviation incidents, we have also proposed corresponding corrective and preventive measures and has finalized them in the first quarter of 2021.

Internal GMP/GDP quality training

Internal audits

- Conducting internal audits at least once every month
- Each department undergo internal audits at least once a year
- For non-conformities in the audit, a CAPA plan must be proposed and related tasks completed within the corresponding prescribed date according to the level of deficiencies.

External audits

- Undergoing governmental GMP inspection every 2-3 years.
- The first protein biopharmaceutical factory in Taiwan to obtain EMA certification.
- The short-, medium- and long-term goal is to pass the regular GMP inspections.

As we believe that personnel is an essential requirement for maintaining quality operation and management, we attach great importance to the quality training of employees. Through annually continued training courses, we aim to help all PharmaEssentia employees understand that quality is closely related to them and to instill the concept of quality management into their routine operations. In 2020, the central axis of internal quality training will focus on the relevant regulations from FDA. Besides internal training, PharmaEssentia also appoints colleagues to participate in external training sponsored by related domestic and foreign academics/associations and hires senior foreign consultants to visit the factory every year to update the knowledge of GMP or laws and regulations for the colleagues in the factory.

2020 quality audit/factory inspection/relevant verification records

Audit/inspection/verification date	Audit/inspection/verification department	Audit/inspection / verification process, key observation items	Audit/inspection/verification results
2018/11/28~2018/11/29	TFDA	Routine GMP Inspection for DS (API)	Extend GMP certification
2019/10/7~2019/10/9	EMA (AGES)	Routine GMP Inspection for DS (API)	Extend GMP certification
2019/10/21~2019/10/23	TFDA	Pre-approval GMP Inspection for Medicinal Product (Preparation filling plant)	Obtained GMP certification (new Preparation filling plant)
2020/1~2020/12	Internal audits	A total of 12 internal audits were carried out in 2020	Completed all

Statistics of GMP related education and training in 2020

Training topic	Sessions	Participants	Training hours
2020 GMP training	17	894	15,198
Regulation, manufacturing, or new employee quality-related GMP training	41	501	20,541
Prevention and correction training	78	970	37,830
External training	24	34	4,896
Total	160	2,399	78,465

3-4

Excellent manufacturing and production

The 3 main facilities of PharmaEssentia are the PEG manufacturing plant, DS manufacturing plant, and aseptic preparation filling plant. The Taichung manufacturing plant is the first biological preparation plant in Taiwan to pass the EMA inspection and obtain GMP certification. The aseptic preparation filling plant also received TFDA GMP and GDP certification in April 2020 and was certificated in the MFDS GMP audit in January 2021. In addition to external inspections, PharmaEssentia's Taichung plant completed 12 internal audits in 2020.

Advanced and high-standard plant equipment

The Company is actively preparing for the FDA inspection. We have received approval from the Taiwan health authorities to apply for the relevant pandemic prevention package for FDA officials to visit Taiwan. In addition, we have hired former FDA officials as factory inspection consultants to prepare for factory inspections.

Passed EMA factory inspection

(extension)

Passed the TFDA factory inspection

(Extension and new aseptic preparation filling plant)

Passed MFDS audit

(new)

FDA come to Taiwan to inspect the factory

(Actively preparing)

Three Main Facilities of PharmaEssentia



PEG
Manufacturing Plant



DS
Manufacturing Plant



Aseptic Preparation
Filling Plant

A manufacturing process with international standards

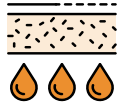
Our product, Ropeginterferon alfa-2b (P1101), is manufactured in 4 primary process stages. Drug Substance (DS) is done first, followed by the filling and packaging process. Each step strictly follows GMP regulations, international standards of quality management, and standard operating procedures.



The Taichung plant's emergency response mechanism is implemented following the "Emergency Response Management Standards for Plant Facilities." When incidents that may cause harm to the factory due to natural disasters and equipment abnormalities occur, they can be handled correctly and effectively to ensure the regular operation of the equipment and all personnel can operate in a safe and secure working environment.

The highest quality aseptic filling and packaging process

After Ropeginterferon alfa-2b (P1101) DS goes through the 4 previously mentioned processes, the filling and packaging operations are carried out according to market demand. The Company's filling and packaging operations can be divided into 3 processes: dispensing and sterile filtration, sterile filling, labeling, and packaging. Taking the Taiwan market as an example, 百斯瑞明® will be sold in the form of fillings. In the filling process, the high-quality production requirement of "aseptic processing" is essential. "Aseptic processing" means that all materials or containers that encounter the product must be sterilized individually, and the final product will be filled and sealed in a very high-quality environment. As incomplete fixed products may cause serious harm to the lives and health of patients, aseptic processing and manufacturing processes are some of the most challenging tasks in the pharmaceutical industry.



1. Dispensing and aseptic filtration

- The high-concentration API Ropegin-terferon alfa-2b (P1101) is adjusted and diluted, and the sterile is filtered before filling.



2. Aseptic filling

- Filling with fully automatic pre-filled syringe. Filled products are put into storage after performing 100% appearance inspections.



3. Labeling and packaging

- Placing the label on the pre-filled syringe, and placing the relevant package inserts, plungers, finger flanges, and needles together into the box.

Management of contracted process

PharmaEssentia’s US filling plant

passed FDA inspection

Due to different market demands and filling and packaging operations at the Taichung Aseptic Preparation Filling Plant, the Company also contracted the US and German factories to fill and package supplies to local patients. To ensure that the operations performed at the commissioned manufacturing site comply with the GMP specifications and the Company's standards, the outsourcing manufacturing plants all passes the process of the Company's supplier verification. The verification and evaluation mechanism includes written data review, on-site audits, and signing of Quality Agreements. Only after the evaluation result meets the quality requirements and is judged as a qualified manufacturer by the QA department can the contracted manufacturing operation be started. Regarding the contracted supplier management and the initial supplier evaluation mechanism, the Company also regularly monitors the service quality of suppliers to control the production to effectively maintain the highest quality requirements. Pyramid Laboratories Inc., a US filling plant, has passed the FDA inspection in early 2021. The overall inspection operation proceeded smoothly, and there were no severe or significant deficiencies. FDA will provide an evaluation report per its schedule.

Improvement of the following generation process

In addition to maintaining the process and product quality through high-quality equipment, professional personnel, internal and external inspections, and other mechanisms, PharmaEssentia also continuously optimizes and improves the function to reduce process risks and improve the success rate process. In 2020, a series of process improvement activities were carried out for the upstream fermentation and downstream purification processes.

Cases of PharmaEssentia's Process Improvement in 2020		
Process phases	Goals	Methods and Outcomes
Fermentation	Increase E. coli production yield.	Feeding into the fermentation tank after pre-cultivation shortens the time efficiency by 23% and increases the yield by about 5.2%.
Purification	Reduce the risk of process contamination and increase the process success rate.	Changed the process from "open operation" to "closed operation" to improve process stability and increase the success rate.

3-5

Safe and stable transnational logistics and transportation

Product shipment and distribution system

PharmaEssentia has set up a “Storage and Transportation Policy” to establish storage and transportation procedures to ensure that all raw materials, intermediate products, and products are stored in a suitable storage environment and management and maintain good quality in the transportation and marketing process. In addition, we have established the “Product Distribution Management Procedures” to establish the distribution procedures and tracking mechanism in compliance with PIC/S GDP requirements. It also specifies that the product’s recipient, such as the contracted filling plant, medical institution, or distributor, must be an approved entity. Furthermore, we have established the “Import, Export and Transportation Management Procedures” to establish the import, export, and transportation procedures to deliver the goods to the designated destinations in a compliant, fast and safe manner. From the time a drug leaves the factory to the time it reaches the patient, PharmaEssentia strives to ensure that the company controls the global distribution of drugs and to prevent the illegal flow of counterfeit, banned, and substandard drugs into the supply chain to protect the safety of patients’ use of drugs.

Warehouse Management

Regarding the storage management of intermediates, raw materials, and drugs, we have established the “Standard Operating Procedure for Warehousing and Storage Management” to establish standard operating procedures to ensure product quality is not affected under any activities or environment. From the Taichung production plant, the storage facilities, and equipment within the plant to the suppliers and gear used for transportation, all must be verified by our QA department to ensure the quality of their services under the standards of current GMP regulations. It also applied in external organizations (e.g., user units, consigned storage units, consigned processing units).

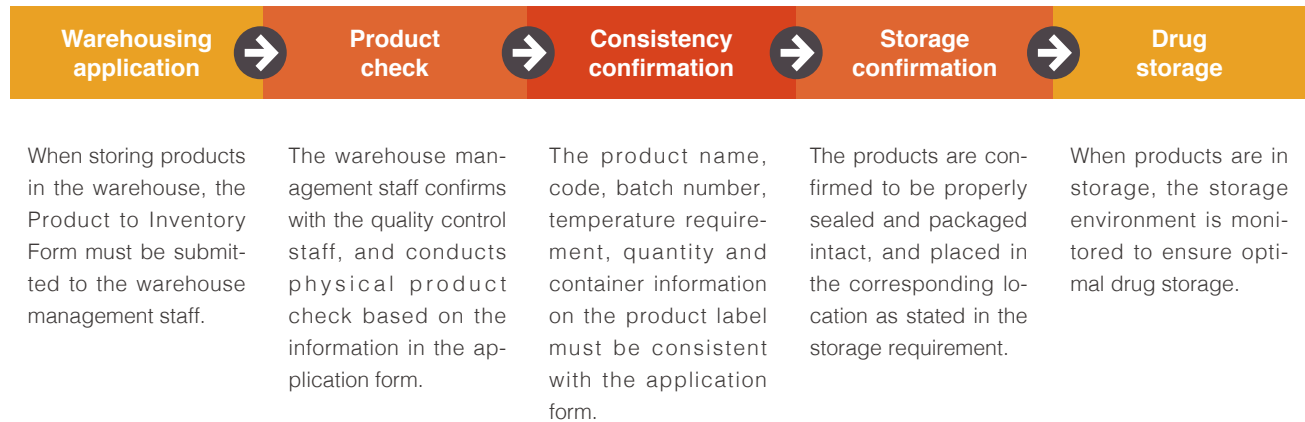


Figure 11: Product warehousing and storage operation flow.

Quality control of shipment and transportation

We have established the "SOP for Product Shipment" to shipment DS products and DP products; we have established the "SOP for Product Shipment" The scope of its application includes the operation of product from the Taichung plant of Pharma-Essentia, or the packaging before transportation from the Taichung plant to the contracted manufacturing factories/storage factories. During the production, supply chain, QA department, and warehouse management personnel strictly control each stage to ensure that each operating procedure is verified and validated to meet GDP requirements. As a result, the products can be delivered to the designated destinations in compliance, quickly and safely, for the patients' medicine use safety.



Quality control of packaging operations

The warehouse management personnel are in charge to ensure that the clean state and temperature in the distribution container meet the product storage conditions and to place the temperature recorder in the container for temperature monitoring. Taking the Ropeginterferon alfa-2b (P1101) as an example, it is necessary to ensure that the product is stored within the temperature range of 2°C to 8°C.



Quality control of distribution

Product distribution are implemented in accordance with the Storage and Distribution Policy with the goal to establish appropriate storage and distribution procedures. Before actual distribution, a scenario simulation analysis is performed to confirm how to keep cold and the required thermal equipment. And regular verification is conducted to ensure that all raw materials, intermediates and products can be well stored for distribution.



3-6

Effective pharmacovigilance and recall mechanism

Materiality Topic

Management approach on patient safety

To ensure the safety of patients after the drugs are marketed, PharmaEssentia established a "Pharmacovigilance mechanism" in 2021 to continuously monitor and control the security and risk of new drugs after their launch. The Company will continue to establish a comprehensive drug safety monitoring system and continuously optimize drug safety-related policies and internal SOPs to safeguard patient health and safety.

GRI 103-2

GRI 103-3

SASB HC-BP-250a.1~a.5



Policies

Internal Policy

1. Regulations of Drug Safety Monitoring
2. Pharmacovigilance Management Regulations
3. Standard Operating Procedures for Pharmacovigilance

External Compliance

1. Rules for Drug Safety Monitoring
2. Pharmaceutical Affairs Act
3. ICH E2A-E2F: Pharmacovigilance
4. EU Guidelines on good pharmacovigilance practices (GVP)



Commitments

We will continue to refine and build a complete pharmacovigilance system by the requirements of professional pharmaceutical quality. The headquarter and subsidiaries are committed to complying with the "Pharmaceutical Affairs Act" and the "Regulations for Drug Safety Monitoring" to proactively collect and regularly report safety information on marketed products and establish a global real-time notification mechanism.



Responsibilities

- Physicians and drug safety monitoring personnel, Pharmacovigilance function team, and clinical trial QA of each subsidiary and other drug supply countries or regions
- Executive Center for Corporate Sustainability - Product Quality and Patient Safety Taskforce



Resources invested

Personnel/operational input:

- Set up clinical trial QA and Pharmacovigilance function in Taiwan headquarter, responsible for drug safety monitoring and management.
- The physicians and drug safety monitoring personnel of each subsidiary where pharmaceutical products are supplied are responsible for drug safety monitoring in those countries or areas. That aim to ensure that drug safety monitoring and reporting are conducted by following the regulations of those, including collecting, evaluating, and reporting adverse drug events or reactions and providing regular safety reports from the regulatory units of each country.

Expense input:

- In 2021, we have budgeted approximately NT\$10 million for global pharmacovigilance.



Goals and targets

2021 short-term goal

1. Complete the formulation and implementation of pharmacovigilance management regulations and standard operating procedures for pharmacovigilance at the headquarter in the first quarter of 2021.
2. Complete the establishment of a post-marketing drug safety database in the first quarter of 2021. The implementation rate of drug safety information reporting reaches 100%, and the implementation rate of drug safety information reported by subsidiaries to headquarters in the required time frame to achieve 100%.
3. Drug safety personnel will be designated at the Taiwan headquarters in the first quarter of 2021 to be responsible for pharmacovigilance and management.
4. Complete the establishment of the drug safety mechanism at the headquarters in the first quarter of 2021. The establishment of the drug safety mechanism in the countries or regions where the subsidiaries and other pharmaceutical products are supplied will be completed according to local regulations and drug marketing schedules.

2022~2024 mid-term goal

1. Continuously review pharmacovigilance management regulations and standard operating procedures for pharmacovigilance and update or revise the content according to the actual situation. The pharmacovigilance of each subsidiary and other countries or regions where pharmaceutical products are supplied are responsible for establishing standard operating procedures following local regulations and drug marketing schedules.
2. Continuously commission CROs to maintain safety databases and provide accelerated and periodic reports on drug safety monitoring. Achieve the implementation rate of drug safety information notification to 100%, and its reporting to headquarter by the drug safety monitoring personnel of each subsidiary and other countries or regions where pharmaceutical products are supplied to 100% under the required timeline.
3. Continuously conduct a drug risk assessment and risk control by the drug safety department in the countries or regions where the headquarter and subsidiaries, and other drug suppliers are located, with an annual implementation rate of 100%.
4. Collect safety information from post-marketing safety reports or academic literature and continuously analyze the correlation between drugs and adverse reactions, with an annual implementation rate of 100%.

2025 to the long-term goal

1. Continuously commission CROs to maintain safety databases and provide accelerated and periodic reports on drug safety monitoring. Achieve the implementation rate of drug safety information notification to 100%. The implementation rate of drug safety information is supplied to 100% in the required time frame. That information is reporting to headquarter in the countries or regions where our subsidiaries and other pharmaceutical products.
2. Develop a drug Risk Management Plan and conduct ongoing drug risk-benefit assessment, with a 100% implementation rate.
3. Collect safety information from post-marketing safety reports or academic literature and continuously analyze the correlation between drugs and adverse reactions, with an annual implementation rate of 100%.



Mechanisms for evaluating the effectiveness of the management approach

Management Assessment Mechanism

- Clinical trials/post-marketing safety monitoring is carried out by the responsible CROs and designated medical monitors. Physicians and drug safety monitors monitor Post-marketing product safety information in the countries or regions where the subsidiaries and other pharmaceutical products are supplied.
- Internal audits: audited by the QA department or commissioned by a third party. External audits: drug safety audits by international and domestic regulatory authorities.

- Establish immediate reporting mechanisms:
 - Adverse reaction notification for headquarter and subsidiaries: Safety@pharmaessentia.com
 - Outsourced CRO's global adverse reaction notification box: PharmaEssentia.drugsafety@covance.com
- Submitting annual drug safety reports and immediate drug safety notifications to the FDA, EMA, TFDA, and other units yearly.
- Strategic partner AOP Orphan aggregates regional security information for Europe every three months.



Mechanisms for evaluating the effectiveness of the management approach

2020 Assessment Results

- Clinical trials/post-marketing safety monitoring: No severe adverse reactions occurred after released the product Ropeginterferon alfa-2b (P1101).
- There was no inspection by any regulatory unit in 2020.
- Regular safety report: submitted the Development Safety Update Report (DSUR) to the competent authorities of various countries following regulations.
- Safety data reconciliation: AOP Orphan provided safety data regularly and exchanged Periodic Safety Update Reports (PSUR) regularly before the time required by regulatory authorities to conduct safety data reconciliation.

Global pharmacovigilance and safety reporting procedures

The primary task of pharmacovigilance is collecting adverse reaction events, proceeding to case evaluation, safety signal detection, and problem analysis, and then further to risk factor analysis, risk assessment, and initiation of preventive measures and management. Therefore, establishing a comprehensive post-market safety monitoring system for drugs is essential for maintaining patients' health.

To understand drug safety matters arising in large-scale clinical patients after the drug has been marketed, PharmaEssentia has contracted with CROs to establish the drug safety monitoring mechanism and formulate standard operating procedures to continuously monitor post-marketing drugs' safety aim to fulfilling the Company's responsibilities for products and patients.



Organizing a Pharmacovigilance Function team

The headquarter collects information regarding drug safety and compiled it into the "Periodic Safety Update Report (PSUR)," and report relevant issues.



Building a cross-country safety Database

Collecting various post-marketing safety information through CROs to establish a multinational integrated Safety Database.



Formulating drug safety notification procedure

If we receive any problems related to the safety or drug use from the hospital, CROs and subsidiaries around the world are required to report to the Pharmacovigilance team at the headquarter and take the initiative to notify the health authorities in accordance with local regulations. The goal is to provide prompt follow-up treatment within the shortest possible time.



Set up an adverse reaction notification mailbox

- Taiwan headquarter has set up an adverse reaction notification mailbox: Safety@pharmaessentia.com
- CRO sets up global adverse drug reaction notification mailbox: PharmaEssentia.drug-safety@covance.com

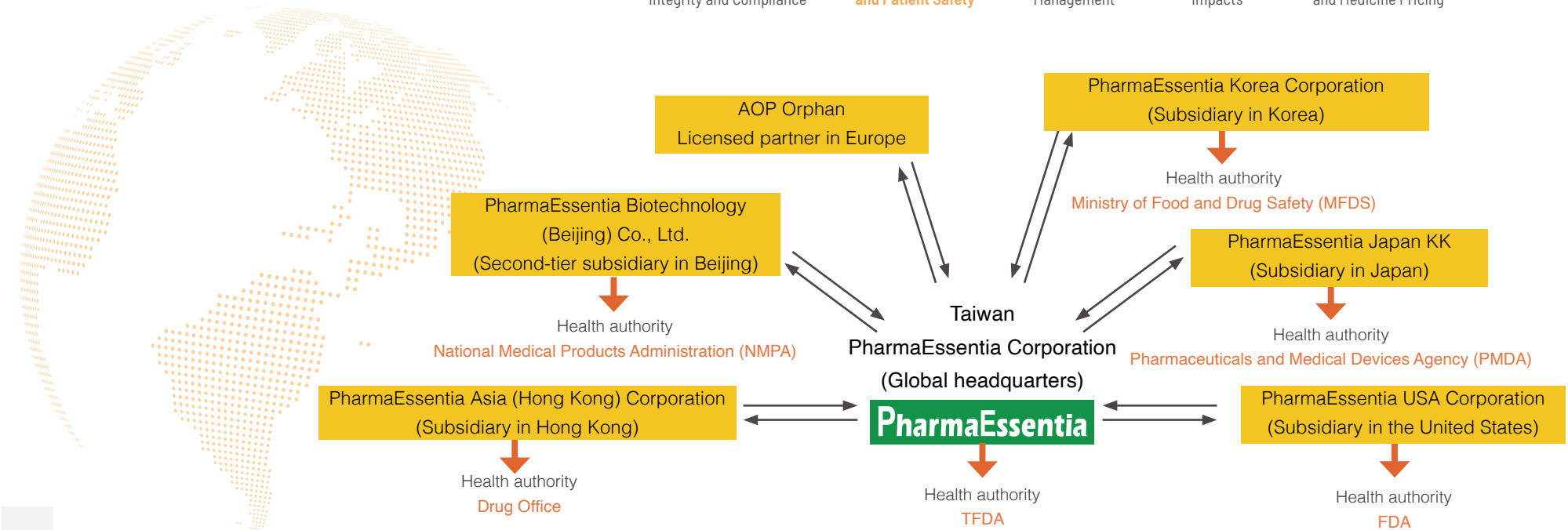


Figure 12: Global drug safety reporting system of PharmaEssentia's product, Ropoginterferon alfa-2b

Pharmacovigilance mechanisms

In 2021, the Taiwan headquarter of PharmaEssentia formally established the " Pharmacovigilance function ." The function is subordinate to the medical research department and has a director-level supervisor and team members. The chief medical officer and the director of pharmacovigilance of the headquarter cooperate with other medical clinical units, Taichung plant, quality department, pharmaceutical regulations, marketing, and IT jointly implement drug safety monitoring work, and the operation process is carried out under the " Standard Operating Procedures for Pharmacovigilance."

In addition to the Taiwan headquarter, each subsidiary or region (the United States, Japan, South Korea, China, Hong Kong, Singapore, Vietnam) also has full-time personnel responsible for pharmacovigilance-related tasks to ensure the collection and notification global drug safety information, etc. The work is carried out perfectly. We have also contracted international CROs to conduct reporting following the regulatory requirements of each country or region and completed the establishment of the safety database by December 2020. Starting from September 2020, the headquarter and each subsidiary or responsible regional personnel will have weekly follow-up meetings with the CRO to ensure that the CRO complies with the regulations of each country and region to carry out timely and regular safety notifications. By the end of 2020, a total of 15 drug safety monitoring meetings were held. In November 2020, PharmaEssentia submitted the first Periodic Safety Update Report(PSUR) of Ropoginterferon alfa-2b (P1101) to TFDA and will continue to provide PSUR to TFDA per regulations. The surveillance period will expire in 2026.

Training of patient safety reporting

Following drug safety regulations, PharmaEssentia entrusts its CROs to develop and implement patient safety management and regulatory unit reporting programs, and holds regular employee training of patient safety notification and maintains all training records. In 2020, we had the company-wide annual training of employee drug safety notification, and all new employees underwent patient safety reporting training within one month after onboarding.

Internal/external training	Type	Description
Expatriate training	Domestic training	The department prepares the budget for training, and employees can choose to attend patient safety training courses/seminars organized by domestic organizations.
	Foreign training	To absorb foreign drug safety knowledge, skills, and training talents, the company will be depending on practical needs, assign personnel to participate in education and training courses organized by foreign institutions.
Internal training	Pre-employment training	Conduct training related to drug safety notification and record training hours and course information when new employees are on board.
	Other training	To enhance employees' professional knowledge and skills in drug safety, we conduct annual training on patient safety reporting.

Patient safety risk management

Following the principle of risk management, PharmaEssentia takes the initiative to identify known risks, detect potential risks, and continue to track significant deficiencies in the safety of marketed drugs to ensure patient safety. At this stage, PharmaEssentia focuses on the assessment of safety risk assessment of the drug after marketing. It adopts the CROs' drug safety risk standard operating procedures and entrusts the CROs' formulation of risk management plans. For the Taiwan market in the future, PharmaEssentia will draw up different levels of risk management content. The content includes patient medication instructions, medical personnel notifications, and special risk prevention measures based on the templates provided by the TFDA and formulate a "Risk Management Plan" based on the features of other product safety.

After the drugs are marketed, sufficient actual clinical use data is collected to evaluate whether patients have chronic side effects after long-term drug use. Such data will serve as the basis for the "Drug Risk and Benefits Evaluation." We regularly review the effectiveness of the risk management plan to reduce the risk of drug use and strive to ensure the safety of medication users.



Product traceability mechanism

SASB HC-BP-260a.1

Effective trace mechanisms can ensure the safety of patients' administration, reduce the risk of counterfeit, prohibited, and substandard drugs entering the legal supply chain, and timely identifies and effectively recalls drugs with quality doubts to provide patients with more safety and protection. PharmaEssentia has established a product traceability mechanism for the global supply chain to ensure the traceability of pharmaceutical products. For this reason, we have formulated the "Product Code and Batch Number Coding Procedures" and "Batch Record Review and Product Release Procedures," which detail the drug number, batch number, and factory activity records of each batch of pharmaceutical products to ensure the basic principles of product batch number coding such as lot flow and traceability, as well as the operational procedures for

product lot release. To establish more comprehensive traceability of pharmaceuticals, we have also actively introduced the serialization of drugs. Internal "Product Secondary Packaging and Serialization Batch Record" has been found to regulate the operation process of commercial packaging and serialization of products by overseas outsourcing factories so that the flow and usage records of individual products can be fully traced even for large quantities of products. BESREMi®, which was expected to be available in the U.S. market, completed for serialization in 2020. In the future, Pyramid Laboratories Inc. will be responsible for the packaging and serialization of pharmaceutical products to comply with the FDA's Drug Supply Chain Security Act (DSCSA).

Drug recall mechanism

SASB HC-BP-260a.2

PharmaEssentia has established a comprehensive drug recall mechanism by incorporating a product traceability system. When the quality of a product is in doubt, a drug recall mechanism can be completed quickly and effectively, providing patients with additional protection for patient safety. We also hold drug recall drills every year to ensure the accuracy and proficiency of recall operations.



When to start

When the product has known or possible manufacturing defects, deterioration, counterfeits or any other serious quality problems.



Recall procedure

QA department initiates the recall procedure in accordance with the Procedure for Return and Recall and proposes the "Recovery Plan Application Form" to initiate actions.



Report to competent authorities

According to the hazard level of drugs, we remove the drugs from the user-end within a certain period, properly dispose of the recovered product, and notify the local competent authority.

Chapter 4

Human Capital Management

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Chapter 4

Human Capital Management

Summary of Chapter 4

Highlights of 2020

Excellent human resources are the cornerstone of a company's sustainable operation and the key to the pursuit of excellence. In addition to creating shared value in the global industry and society, PharmaEssentia is committed to building a healthy and friendly work environment with a comprehensive welfare system and competitive compensation. Through the aforementioned actions, we attract and form a high-quality professional team with professionals in biotechnology and experts interested in participating in the international and world-class biopharmaceutical industry, work hard together, and move forward with all employees. To cultivate professional tal-

ents that meet the Company's needs, the Company provides staff training courses and rich, diversified learning resources based on its vision and strategic goals through global business expansion and learning from international partners to enhance employee development and corporate competitiveness. In occupational health and safety for our employees, we regularly conduct training, emergency response drills, and various workplace health promotion activities. In the past three years, we have maintained an excellent record of zero occupational accidents, demonstrating our success in creating a safe, healthy, and happy workplace environment for our employees.



Relevant material topics



Talent cultivation and career development



Occupational health and safety

Relevant stakeholders



Employees



Suppliers/contractors

Performance highlights

100%

The percentage of newly hired senior supervisors above the managerial level that are local Taiwanese talents.

50%

Nearly 50% of colleagues have been working for more than five years.

100%

The reinstatement rate and retention of employees after parental leave.

70%

Nearly 70% of our employees hold master's and doctoral degrees.

100%

Completion rate of employee performance assessment.

100%

Maternal health protection program implementation rate.

90%

Percentage of retention rate of new hires.

0

occupational accident

NT\$ 3.09 million

Total employee benefits expense.

4-1

A happy workplace

Create a stable and motivating talent environment

The impact of COVID-19 swept across the globe in 2020, testing how companies worldwide can make the most appropriate workforce arrangements and adjustments in time to respond to the changes in the workplace culture and environment. According to the "2021 Global Culture Report," released in September 2020 by OC Tanner, a software services company specializing in employee recognition, a survey of 40,000 workers in 28 countries worldwide found significant decreases in all indicators of corporate motivation. Therefore, with the launch of critical clinical trials for ET in many countries and the obtaining of marketing licenses in Europe, Taiwan, and Israel, it was crucial for PharmaEssentia to continue to recruit promising and qualified personnel and at the same time to stabilize the internal forces to position itself for sales in the global market. To create a stable working environment for retaining talents, we encourage the development of internal talents through compensation and benefits, friendly atmosphere, humane management, smooth internal rotation and training, development, and attracting new talents from outside to inject innovative energy and forward momentum PharmaEssentia continuously. Through regular surveys on new hires, the Company can better understand their company's expectations to strive for improvement. We also systematically nurture and select quality talent through corporate internships and government project partnerships to support our global deployment strategy and promote the sustainable development of our talent.

PharmaEssentia has subsidiaries in the United States, Japan, China, Hong Kong, and South Korea. The workforce structure in Taiwan and the U.S. also highlights the three main characteristics of our human resources: global presence and localization of talent promotion, gender equality and tolerance, and stable retention of talented people.

**Globalizing our operations
Localizing our talent acquisition**



100%

Newly hired senior executives at the managerial level and above are local talents in both Taiwan and the US.

**Gender Equality and
Inclusiveness**



Gender-balanced

Same number of male and female employees in Taiwan and the US.

**Outstanding talents
High retention rates**



High retention rate

Nearly 50% of senior employees with more than 5 years of experience in Taiwan headquarters and Taiwan subsidiaries.



GRI 102-8 GRI 202-2 GRI 405-1

Manpower Structure of Taiwan in 2020 <small>(Note 1)</small>							
Category	Sub-category	Male		Female		Total	
		No. of person(s)	As a percentage of sub-category	No. of person(s)	As a percentage of sub-category	No. of person(s)	As a percentage of total employees
By job type	R&D	32	53%	28	47%	60	28%
	Manufacture and production	63	58%	46	42%	109	50%
	Administrative	15	31%	33	69%	48	22%
By position <small>(Note 2)</small>	Operational management directors(Vice President and above)	4	67%	2	33%	6	3%
	Senior-level supervisors (department directors and above)	8	57%	6	43%	14	6%
	Middle-level supervisors (managers and above)	11	58%	8	42%	19	9%
	Junior-level supervisors (team leaders)	18	67%	9	33%	27	12%
	Staff level	69	46%	82	54%	151	70%
By age	< 30 (incl.)	8	38%	13	62%	21	10%
	30 - 50 (incl.)	89	52%	82	48%	171	79%
	> 51 (incl.)	13	52%	12	48%	25	11%
By educational background	PhD	21	72%	8	28%	29	13%
	Master's	59	49%	61	51%	120	55%
	Bachelor	28	47%	32	53%	60	28%
	Others	2	25%	6	75%	8	4%
By seniority	< 1 year	13	43%	17	57%	30	14%
	1 - 3 years	20	43%	26	57%	46	21%
	3 - 5 years	21	57%	16	43%	37	17%
	5 - 10 years	44	56%	34	44%	78	36%
	10 - 20 years	12	46%	14	54%	26	12%
Total <small>(Note 3 and 4)</small>		110	51%	107	49%	217	100%

Note 1. The data in this table cover the Taiwan headquarter and subsidiary Panco Healthcare Co., LTD.

Note 2. Among the positions, middle-level managers and above are senior supervisors.

Note 3. All employees of PharmaEssentia, the headquarters in Taiwan, and Panco Healthcare, a subsidiary in Taiwan, are staff employees (indefinite contract employees).

Note 4. At the end of 2020, one employee with mental and physical disabilities worked at the headquarter of PharmaEssentia in Taiwan and its subsidiary Panco Healthcare in Taiwan, which was weighed to two because the employee was a person with severe mental and physical disabilities.

Manpower Structure of U.S. Subsidiaries in 2020 <small>(Note 1)</small>							
Category	Sub-category	Male		Female		Total	
		No. of person(s)	As a percentage of sub-category	No. of person(s)	As a percentage of sub-category	No. of person(s)	As a percentage of total employees
By job type	R&D	4	44%	5	56%	9	26%
	Manufacture and production	8	62%	5	38%	13	38%
	Administrative	7	58%	5	42%	12	36%
By position <small>(Note 2)</small>	Operational management directors(Vice President and above)	3	50%	3	50%	6	18%
	Senior-level supervisors (department directors and above)	11	73%	4	27%	15	44%
	Middle-level supervisors (managers and above)	1	50%	1	50%	2	6%
	Junior-level supervisors (team leaders)	-	-	-	-	-	-
	Staff level	4	36%	7	64%	11	32%
By age	< 30 (incl.)	1	20%	4	80%	5	15%
	30 - 50 (incl.)	11	55%	9	45%	20	59%
	> 51 (incl.)	7	78%	2	22%	9	26%
By educational background	PhD	4	80%	1	20%	5	15%
	Master's	9	47%	10	53%	19	56%
	Bachelor	6	67%	3	33%	9	26%
	Others	-	-	1	100%	1	3%
By seniority <small>(Note 3)</small>	< 1 year	16	59%	11	41%	27	79%
	1 - 3 years	3	43%	4	57%	7	21%
Total <small>(Note 4)</small>		19	56%	15	44%	34	100%

Note 1. The data in this table covers only the U.S. subsidiary.

Note 2. Among the positions, middle-level managers and above are senior supervisors.

Note 3. All employees of U.S. subsidiaries are staff employees (indefinite contract employees).

Note 4. The U.S. subsidiary was established in 2018, so it has not employed employees for more than three years.

New hires and retentions

SASB HC-BP-330a.1~a.2

PharmaEssentia has been recruiting biomedical and R&D talents in various professional fields, like medical clinical and international management professionals. Besides that, we are also actively deploying its global subsidiaries' commercial operation human resources to meet the milestone of globalization and continuous development of innovative new drug research and development. We select employees based on their ability to perform their core competencies. We use diverse and open recruitment channels to choose suitable candidates in the spirit of non-discrimination and fair treatment. In 2020, we recruited more than 30 new R&D and medical research professionals worldwide, accounting for 10% of our total workforce. The retention rate for executive positions in 2020 was 93.94%, so the growth rate of all PharmaEssentia's employees has been growing steadily in the past three years. In recent years, the number of new female employees has been higher than that of new male employees. It is concentrated in the group under 30 years old, which shows that we fully provide employment opportunities for women and build a diversified workplace. In addition, to stimulate organizational revitalization and cultivate a full range of talents, when new business needs arise or critical job vacancies arise, we will also prioritize staff rotation evaluation. Those who have served at least 2 years in the current unit with excellent performance can apply for the job based on their characteristics, expertise, and desire to transfer department. For colleagues who propose to resign, the supervisor must conduct interviews with each resigned employee to understand the reasons and room for improvement. We also provide talent retention programs at appropriate times to reduce the turnover rate and stabilize the continuous retention of outstanding talents.

GRI 401-1

2019 and 2020 new regular hires and employee turnover								
Category	2019				2020			
	New hires		Employee turnover		New hires		Employee turnover	
	Male	Female	Male	Female	Male	Female	Male	Female
< 30 (incl.) of age	5	5	-	3	4	5	2	2
30 - 50 (incl.) of age	17	6	11	4	8	13	12	6
> 51 (incl.) of age	-	-	1	1	3	3	2	1
Total	22	11	12	8	15	21	16	9
Percentage of new hires to employee turnover	11.96%	5.98%	6.52%	4.35%	7.35%	10.29%	7.84%	4.41%

Note 1. The data in this table for 2020 covers the Taiwan headquarters and the subsidiary Panco Healthcare, but the data for 2019 does not include the subsidiary Panco Healthcare. In the future, complete data collection and disclosure will continue.

Note 2. Percentage of new hires = 2020 accumulated new hires ÷ (employee number at the beginning of period + end of period) / 2.

Note 3. Percentage of resignees = 2020 accumulated resignees ÷ (employee number at the beginning of period + end of period) / 2.

Growth rate of employee numbers in the most recent 3 years		
2018	2019	2020
7.27%	9.04%	12.44%

Note 1. Growth rate of employee number = (employee number at current year-end - that at previous year-end) ÷ employee number at prior year-end

Note 2. The annual data in this table 3 does not include the subsidiary Panco Healthcare. In the future, we will continue to collect and disclose complete information.

4-2

Competitive compensation and benefits

Competitive and fair salary system

PharmaEssentia is equal towards all employees, and the overall salary does not vary regarding differences in gender, religion, race, nationality, or party affiliation. In addition, to grasp the labor market status in the biotechnology industry and retain outstanding talents and attract external talents, we also commissioned external consulting companies to conduct industry average salary and welfare surveys. Each year, based on the achievement of the Company's annual management goals, the individual's annual performance appraisal and the external salary and benefits survey, performance pay adjustment, promotion pay adjustment, and structured pay adjustment are conducted respectively to provide better salaries the industry level. The average salary adjustment for 2020 is 3.57%. Furthermore, to attract and retain the talents needed for the Company's development, we also use profit-sharing mechanisms to encourage employees' long-term service and enhance their commitment to the company. Such as employee stock options, new shares with restricted employee rights, and cash incremental employee stock options to motivate employees to work with the company to innovate operational performance and create long-term value.

GRI 405-2

Ratio of remuneration and compensation of male employees compared to female employees in 2020 <small>(Note1)</small>			
Type		Compensation	Remuneration
Management	Operational management directors (Vice President and above)	0.86	0.63
	Senior-level supervisors (department directors and above)	1.03	2.15
	Middle-level supervisors (managers and above)	0.81	0.89
	Junior-level supervisors (team leaders)	1.26	1.92
Non-managerial employees	Staff level	1.16	1.34

Note 1: Compensation refers to monthly salary, while remuneration is compensation plus bonus.

Note 2: The data in this table cover Taiwan headquarter and subsidiary Panco Healthcare.

In the past three years, our full-time employees' total salary and average salary, who are not in supervisory positions, have increased significantly. As a result, it fully demonstrates the results of our salary incentive for middle and senior talents and personnel after promotion and the continuous salary adjustment of our junior staff.

GRI 406-1

Information on salary of 2018~ 2020 non-managerial full-time employees <small>(Unit: NT\$ thousands)</small>			
Year	Total salary	Average salary	Median
2018	133,894	853	N/A
2019	175,752	1,046	857
2020	196,378	1,085	853

Note 1: The information in this table has been audited by Ernst & Young.

Note 2: The data in the table only covers the Taiwan headquarter.

Diversified benefit system

GRI 201-3 GRI 401-2

PharmaEssentia established the Employee Welfare Committee in 2013. The Company and the Committee have jointly planned many related welfare activities. In addition to the statutory standards, we provide a diversified welfare system that meets the needs of our colleagues. In particular, we continue to contract with quality childcare providers to meet the needs of our employees in choosing childcare near them. We also strive for more concessions for our employees through group bargaining to effectively reduce the burden of raising children. To encourage employees to have children, the Company provides a childbirth benefit of NT\$ 6,000. With the previous marriage and childcare benefits, employees can achieve work-life balance. In 2020, the total expenses for medical help for Taiwan headquarter and Panco Healthcare's subsidiary amounted to NT\$3.09 million, with 929 claims for various benefits.



Figure 13: Company trip



Competitive salary system

- Holiday cash and gift
- Project incentives
- Employee stock options



Comprehensive insurance plans

- Labor insurance
- Health insurance
- Group insurance
- Overseas business travel insurance



Retirement protection and benefits

- For the employees under the old pension system, 2% of their monthly salary is deposited into the old retirement reserve account of the Bank of Taiwan monthly.
- After implementing the new pension system, the Company allocates 6% of individuals' monthly salary to their pension accounts monthly according to the pension level of employees.
- Retirement farewell dinner party.



Overall employee care

- Health examination
- Weight loss activities
- Massage
- Unpaid leaves
- Health seminars
- Commendation to excellent employees
- Special store offer
- Free taxi rides for evening shifts



Marriage and childbirth care

- Kindergarten cooperation plans
- Leaves related to pregnancy and childbirth, and unpaid parental leaves
- Nursing room establishment
- NT\$6,000 maternity allowance per



Flexible vacation system

- Flexible working hours
- Comprehensive vacation system (partly better than the Labor Standards Act)



Diverse employee activities

- Department dinner
- Club Activities
- Sports activities
- Employee travel

Table of employees applying for unpaid parental leave in the most recent 3 years									
Year	2018			2019			2020		
Item	Male	Female	Total	Male	Female	Total	Male	Female	Total
Number of employees qualified to apply for unpaid paternity leave in the given year (A)	13	8	21	24	15	39	23	11	34
Actual number of employees applied for unpaid paternity leave in the given year (B)	1	3	4	1	6	7	-	5	5
Unpaid paternity leave application rate (B/A*100%)	8%	38%	19%	4%	40%	18%	0%	45%	15%
Number of employees anticipated returning to work after unpaid paternity leave in the given year (C)	-	2	2	1	5	6	-	3	3
Actual number of employees that return to work after the unpaid paternity leave in the given year (D)	-	2	2	1	3	4	-	3	3
The rate of return to work after the unpaid paternity leave (D/ C*100%)	-	100%	100%	100%	60%	67%	-	100%	100%
Number of employees that returned to work after unpaid paternity leave in the previous year (E)	-	2	2	-	2	2	1	3	4
Number of employees that returned to work who continued to work for one year after the unpaid paternity leave in the previous year (F)	-	1	1	-	2	2	1	3	4
The retention rate for parental leave (F/E*100%)	-	50%	50%	-	100%	100%	100%	100%	100%

Note: The data in this table cover Taiwan headquarters and subsidiary Panco Healthcare.

4-3

Human rights protection

Human Right Policy

To fulfill its corporate social responsibility and protect the fundamental human rights of all employees, PharmaEssentia strictly abides by the labor-related laws and regulations in the operating locations worldwide to protect the legal rights and interests of employees. The Company also supports the human rights protections and basic principles outlined in international covenants such as "United Nation Global Compact," "Universal Declaration of Human Rights," and "International Labour Convention." We take our corporate responsibility to respect and protect human rights and treat all paid employees, including contract employees and interns, with dignity and respect. There are no incidents of forced labor, child labor, or discrimination in any form. For more details on the Company's ["Human Right Policy," please refer to the Company's official website.](#)

Transparent internal communication and grievance channels

PharmaEssentia actively creates diverse two-way communication channels for the employees to listen to their voices to build a harmonious workplace environment. We expect internal communication to be seamless and transparent to protect each employee's legitimate rights. The Audit Office keeps the issues and results of each case to ensure proper compliance. There were no cases in the various communication and grievance channels in 2020.



Regular staff meetings and department meetings

Regular two-way communication with colleagues through internal meetings. In addition to announce important company issues and operational goals, it also allows senior management to discuss the company's vision and culture directly with executives and employees, and to build consensus and goals. All colleagues can convey comments or suggestions through this channel.



Internal announcement

The Company's internal system or important information will also be announced in different categories according to the content, so that employees can grasp the information content immediately and achieve zero error in information.



Compensation committee meetings

At PharmaEssentia, we hold regular compensation committee meetings to explain to employee representatives about various issues such as employee health, environmental safety, and welfare, and we announce the minutes of these meetings to our employees. The Taipei headquarter and Taichung branch held 5 meetings each in 2020 respectively.



Prevention of workplace sexual harassment

In order to ensure a gender-friendly workplace, we strictly prohibit any tangible or intangible sexual harassment in the workplace, and have clearly established relevant measures, such as the "Sexual Harassment Prevention and Punishment Measures" and the "Code of Ethics for Employees", etc. We have also set up a sexual harassment prevention and punishment complaint hotline and an e-mail box to protect the information of complainants and to protect the rights of fellow employees. The Company does not have any sexual harassment complaints in 2020.



Complaint channel

The Company has a mailbox for employees' opinions and a mailbox for workplace abuse. Employees can report their complaints through the complaint channel, and the situation will be reported according to the authority and responsibility of each unit.

4-4

Talent training and career development

Materiality Topic

Management approach to talent training

GRI 103-2 GRI 103-3

Talent is an essential asset of the Company and a critical factor in determining the Company's competitiveness. We focus on our core competency and closely integrate our employees' characteristics with the organization's strategic development direction so that each employee can continue to enrich and acquire new knowledge and stimulate their inner potential at work. On the one hand, we can enhance human capital so that human resources can be effectively used to achieve the Company's business objectives. On the other hand, we can help employees deepen their professional fields or refine their management competency to continue to grow in their careers and create a win-win situation.



Policies

It is now implemented by the "Management Regulations for Training" and "Regulations for Talent Recommendation and Award." The formulation of the human resources development policy is expected to be completed in the second quarter of 2021.



Commitments

As the responsibility and commitment of PharmaEssentia to its employees, we will continue to hold training and development programs to retain talents.



Responsibilities

- Talent cultivation and development policy: human resources and management executives
- Responsible unit for talent cultivation: heads of departments
- Execution Center for Corporate Sustainability - Employee Care Taskforce



Resources invested

- Organize internal and external education training and regularly invite experts from leading academic and research institutions to exchange and share innovative new drug development expertise with all colleagues for their learning and development.
- We continue to collaborate with academia and Academia Sinica on projects to refine the expertise and project integration capabilities of our R&D personnel. Each project is On-Job Training and improved competency in Project Leadership Training for R&D personnel.
- Each department uses a mentor system to help pass on experience, reduce the turnover rate of recruits, and train senior colleagues to cultivate talents.
- In the future, expert consultants will be hired to optimize performance evaluation and develop a talent management system. Millions of dollars are expected to be invested in talent training and development.



Goals and targets

2021 short-term goal

1. The training program starts with recruits. The recruits are given training courses to works to let them be familiar with the working environment and bring their strengths into play as soon as possible.
2. Continuous staff skills training by the department head to implement 1-2 skills for staff duties.
3. Review the current status of existing talent professional competencies and complete the definition of professional competencies in each department as a basis for talent development.
4. Provide department heads with 2 training courses of professional competency linked to the performance management system to enhance various professional abilities and improve management performance.
5. Establish the professional competency system of each department to ensure the professional capabilities required for each position. Provide the standards and learning indicators of the employees, and at the same time establish the talent hiring standards.
6. Integrate the department's professional competencies with performance evaluation and project execution, implement performance and function evaluation for all staff, and implement the learning and establishment of professional functions through performance evaluation.
7. Establish a succession system.

2022~2024 mid-term goal

1. Develop and implement a duty rotation system to improve the efficiency of talent transfer by 2%-3%.
2. Establish and implement an internal lecturer system and train 5 to 7 internal lecturers to cultivate talents and establish a knowledge management system to pass on professional knowledge.
3. Conduct first employee satisfaction survey and strengthen critical issues.
4. Implement six executive leadership-related programs from 2021 to 2023, supplemented by a leadership assessment mechanism, to develop succession leadership and increase retention rates.
5. Complete succession talent assessment and plan for the 3-year succession development plan and leadership training
6. Construct 5-year long-term development talents and implement annual KPIs for department heads.
7. Establishing a talent management and talent development system, prioritizing the development of crucial talents and successors, and providing a talent evaluation report to the management team.
8. Translate company culture and core values into actionable employee core competencies (4-5 items), build a learning organization, and refine core competencies.
9. Optimize the organizational development level with the employee satisfaction survey results to continuously improve employee retention and employee satisfaction, aiming to reach the market average.

2025~ Long-term Goal

- Establish a succession system and conduct annual talent leadership evaluations to establish a succession pool and continuously cultivate key talent in line with the Company's long-term goals for sustainable development.



Mechanisms for evaluating the effectiveness of the management approach

Management Assessment Mechanism

- Promotion rate for supervisory positions from internal staff
- Manager retention rate

2020 Assessment Results

- Promotion rate for supervisory positions from internal staff: 58.8% in 2020
- Supervisor retention rate: 93.94% in 2020

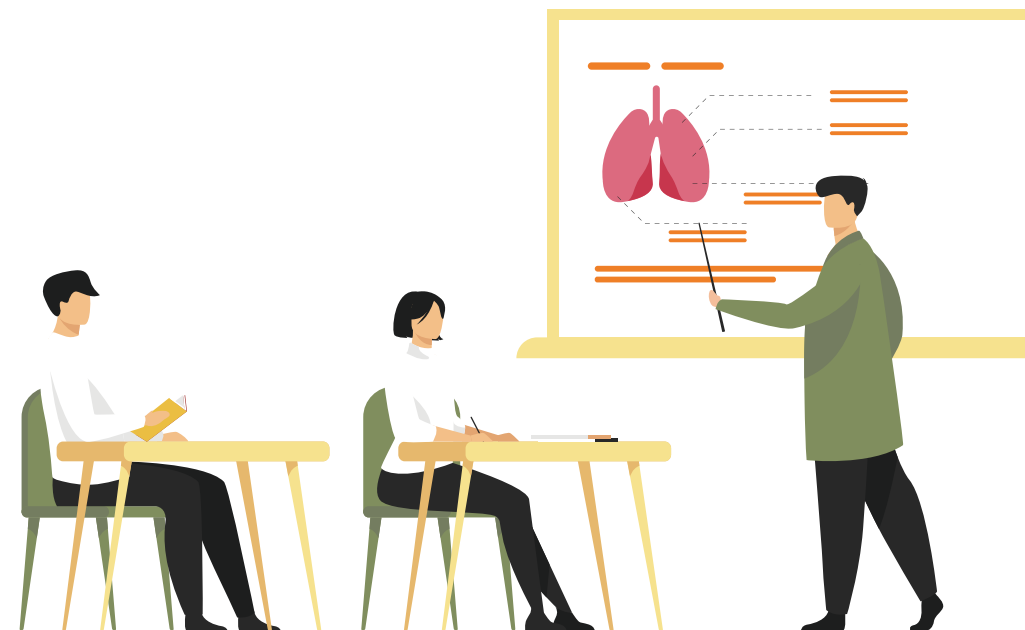
Comprehensive training and development system

Through intensive on-the-job training, multiple learning channels, and overseas training for outstanding personnel, PharmaEssentia enriches our employees and gains new knowledge in the workplace and nurturing the biomedical professionals. In the future, we will hire expert consultants to optimize performance evaluation and develop a talent management system. We expect to invest millions of dollars in talent training and development. Through this process, we will identify key quality talents for focused training. It is complemented by a corporate succession system that allows us to upgrade the efficiency of our human resources management and reserve leadership capability for long-term sustainable management.

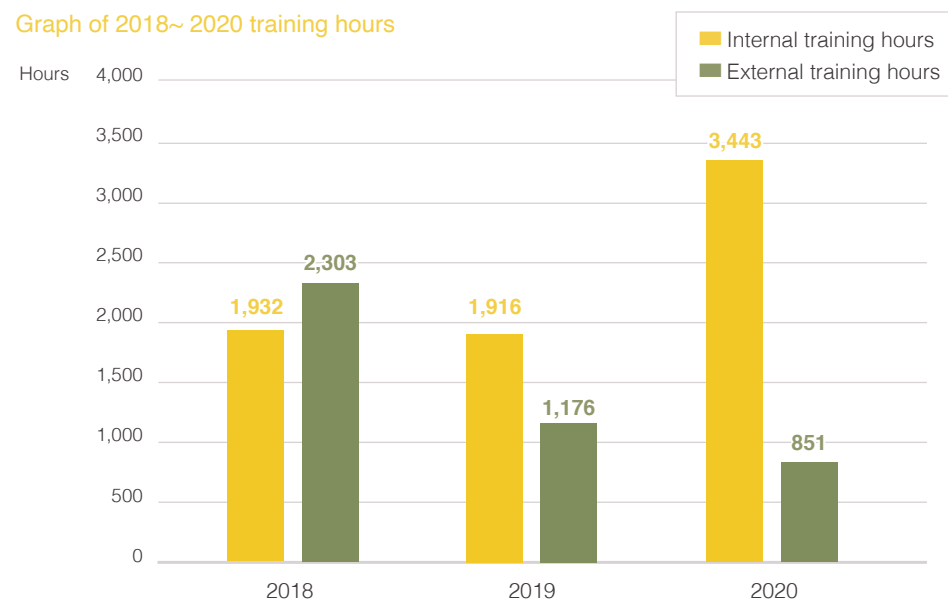
GRI 404-1

2020 average training hours by position and gender (Unit: Hour)		
Category	Male	Female
Average training hours - Operational management directors (Vice President and above)	10.34	9.75
Average training hours - Senior-level supervisors (department directors and above)	14.77	10.49
Average training hours - Middle-level supervisors (managers and above)	20.07	9.12
Average training hours - Junior-level supervisors (team leaders)	22.87	32.21
Average training hours – Staff level	22.82	18.11

Note: The data in this table cover Taiwan headquarters and subsidiary Panco Healthcare.



Graph of 2018~ 2020 training hours



Performance evaluation and promotion system

GRI 404-3

The main goal of the performance management spirit of PharmaEssentia is to drive organizational growth and promote daily communication. Global full-time employees are required to undergo regular performance and career development reviews. We have established a fair and objective performance appraisal system integrated with the Company's strategic development and implemented it in a performance-based compensation system as a reference for colleagues' work goals and personal growth and development. Through the performance appraisal system, we manage the output performance of our colleagues and explore their potential so that we can select talents from it. The annual mid-year interview and the end-of-year appraisal are conducted once a year so that colleagues and supervisors can jointly confirm performance output and target achievement. For those with relatively low-performance results or lagging targets, supervisors need to actively explore the reasons, communicate adequately, teach individually, make appropriate adjustments or support, and jointly formulate improvement plans and estimated completion times. At the same time, the human resources unit arranges to participate in relevant courses to achieve improvement goals. As for colleagues with excellent performance and potential, the annual employee promotion nomination and evaluation will have a better chance of being promoted. We also plan related mechanisms to give colleagues rotation. When internal vacancies occur, we can also recommend suitable internal candidates first, cultivate talents with multiple professional capabilities, promote the continuous retention of internal talents, and give play to cross-departmental communication and coordination capabilities.



Percentage of full-time employees receiving performance and career development reviews in 2020				
Operating locations	Item	Number of employees to be assessed (A)	Actual number of employees assessed (B)	Percentage of assessment (B/A)
Taiwan headquarter and subsidiaries	Male	101	101	100%
	Female	102	102	100%
US subsidiary	Male	10	10	100%
	Female	12	12	100%

Note: Besides employees under the situations such as unexpired probation period, unpaid leaves, etc., all performance assessments have been completed for all positions and both male and female employees.



4-5

Occupational health and safety

Materiality Topic


Management approach on occupational safety and health management

The outbreak of the COVID-19 pandemic in 2020 has prompted us to pay more attention to the prevention of infectious diseases for our colleagues, and therefore strengthen our colleagues' health management and health promotion measures. Only by constructing a safe, hygienic, and healthy workplace and promoting colleagues' physical and mental health can PharmaEssentia work together to create a sustainable future.



GRI 103-2 GRI 103-3



Policies Occupational Safety and Health Policy




Commitments Commit to creating a zero-disaster workplace, ensuring the safety and health of employees, free from the threat of injury and disease.




Responsibilities

- Currently, the Environmental Health and Safety Department is responsible for drafting, planning, supervising, and guiding the implementation of relevant departments. The supervisor of each unit is responsible for commanding and overseeing the implementation of appropriate personnel.
- It is expected that the Occupational Safety and Health Committee will be established in 2021 to review, coordinate and recommend safety and health and other related issues.
- Execution Center for Corporate Sustainability - Employee Care Taskforce



Resources invested The environmental safety team's human resources and maintenance of workplace safety and health expenditures are about NT\$270,000.



Goals and targets

2021 short-term goal	2022~2024 mid-term goal	2025 to the long-term goal
<ol style="list-style-type: none">1. Establish Occupational Safety and Health Committee.2. Taipei headquarter hires full-time occupational safety and health personnel.3. Complete the risk assessment of the high-risk workplace of the Taichung manufacturing plant.	<ul style="list-style-type: none">• Introduce the ISO 45001 occupational safety and health management system, and launch a company-wide complete hazard identification, risk assessment, accident investigation, and other related measures.	<ul style="list-style-type: none">• Optimize the implementation of ISO 45001 occupational health and safety management system certification.



Mechanisms for evaluating the effectiveness of the management approach

Management Assessment Mechanism

- Employee grievances channel and system.
- Central Taiwan Science Park Administration visits the factory irregularly for audit.
- Competent authority audits the implementation of occupational safety and health at Taichung manufacturing sites.
- Internal employee occupational injury.
- Comparison of the pharmaceutical manufacturing industry by the total injury index of each sector.

2020 Assessment Results

- No employee complaint cases.
- No significant deficiencies in the audit by the competent authority.
- There was no occupational injury incident, and the total injury index was lower than the industry.

Workplace Health Promotion

GRI 403-3

Providing a safe and friendly workplace to our employees is our commitment and the fundamental guarantee for them. PharmaEssentia is committed to reducing the risk of occupational injuries and creating a working environment that allows employees to enjoy a balanced, healthy, and happy work environment. We also received the “Healthy Workplace Certification/Health Promotion Label” again in 2020, confirming our employees’ achievement in implementing health protection.



Figure 14: Colleagues participate in health promotion seminars.



Figure 15: Annual health examination.



Figure 16: Healthy workplace certification/health promotion label.

Health examination

Annual safety and health check-ups for early detection of diseases and early treatment

- We assist employees in health management with a frequency of health examination once a year, to identify disease risk factors as soon as possible. There are 163 colleagues in annual health examination.
- For personnel engaged in special hazardous operations, health inspections for special operations are further provided. A total of 74 special health examination were conducted annually. Among them, the colleagues who are classified as secondary management have no relevance to the work through the judgment of professional specialists, and the Company will also arrange nurses or doctors to carry out health education propaganda.

Medical and nursing staff clinical health education services

Contracted nurses to provide health education services, to prevent health abnormalities and to reduce diseases

Arrange interviews with colleagues and health coaching instructions. In 2020, we invited nurses, doctors, physiotherapists and psychologists to visit our factories for health education and promotion. 78 sessions were held in total.

Protection of mother's health

Evaluate hazards that may be reduced or removed to ensure the safety of female employees in the workplace

The implementation is aimed at female employees during pregnancy and less than one year after delivery, and who are engaged in work that may affect the health of the fetus, mother and baby during pregnancy or lactation. Based on the identification, evaluation, and control of workplace or operational hazards, as well as the classification of hazardous chemicals, health protection measures such as changing working conditions, adjusting working hours, and changing jobs are implemented with the help of professional physician's suitability assessment recommendations. The implementation rate of the maternal health protection program for the past three years has been 100%.

Human factors hazard prevention plan

Hazard identification, injury and illness investigation and evaluation to facilitate early detection of injuries and illnesses caused by hazards

According to the 2020 Human Factors Hazard Prevention Questionnaire, there were 20 employees with aches and pains, and one employee was assessed to be at risk for human factors hazards. We will continue to track and improve the program in the first quarter of 2021.

Prevention against diseases from overwork

Hazard identification, injury and illness investigation and evaluation to facilitate early detection of injuries and illnesses caused by hazards

Risk classification is identified and evaluated based on annual health examination reports, attendance forms, and personal and workload assessments, and those with moderate risk after assessment in 2020 will be interviewed by a specialist and followed up with a health care provider.

Implementation of occupational health and safety



Complying with government regulations

Implementing government regulations and promote safety and harmony



Valuing hazards prevention

Seeking zero disasters and providing a safe environment



Implementing continuous improvement

Creating a safe,hygienic and good corporate image



Promoting full participation from employees

Encouraging employee participation and enhancing safety awareness

Workplace safety maintenance in response to the COVID-19 pandemic

In the face of the continuing epidemic in 2020, Pharma-Essentia has established an epidemic response team consisting of the Chairman, CEO, President, Chief Operating Officer, Head of Production and Manufacturing Division, Human Resources and Environmental Safety units, etc. Meetings will be held at any time depending on the pandemic alerts to protect the health and safety of employees. In the future, we will also respond immediately to the announcement of the pandemic threat level and the latest regulations, prepare in advance the system platform that allows employees to work remotely from home, and prepare for the company's return severely impacted by the pandemic.



Example

Our response actions to COVID-19

For plant personnel:

1. Strengthen the promotion of prevention policies.
2. Diversion of the executive staff to avoid cross-contamination.
3. Keep social distancing in the working area.
4. Avoid entering and exiting crowded places.
5. Surveying employees' personal travel history to formulate management measures.
6. Travel control.
7. Strictly requiring employees to take temperature, wear masks, and disinfect hands with alcohol when entering the office.
8. Remote office to avoid cross-contamination.
9. Personnel from the Taichung factory and the Central Taiwan Science Park office are prohibited from contacting and communicating (including off-duty hours) or going to work areas that are not under their standards. The administrative department will send special personnel to assist in the delivery of documents.
10. Suspend primary training (except the requirements by regulations).
11. Prioritize video conferences to avoid group gathering and cross-contamination.

For external personnel:

Reducing unnecessary visits. Visitors are restricted to the office area to prevent visitors from entering the production area.

Note: The above control measures will follow the pandemic threat level announcement and the latest regulations.

Mechanism of workplace safety and accident prevention

GRI 403-5

GRI 403-7

GRI 403-9

GRI 403-10

To respond to various emergencies and prevent industrial safety incidents, the Company has formulated the “Labor Safety and Health Work Rules” and “Procedures for Emergency Responses” to ensure environmental safety and employees’ health. Our employees receive regular protection and on-the-job health training. Regarding the operation items or operation supervisors as stipulated by laws and regulations, personnel shall be delegated according to law, and non-operators shall not be allowed to operate these operation items.

27 sessions 205 participants

Internal and external occupational safety and health staff training

0

occupational accident

According to the data on the occupational injuries of PharmaEssentia and subsidiary Panco Healthcare in 2020, the Disabling Injury Frequency Rate, the Disabling Injury Severity Rate, and the Frequency-Severity Indicator are all 0. Compared to the data Frequency-Severity Indicator of pharmaceutical manufacturing industry published by the Occupational Safety and Health Administration, Ministry of Labor, PharmaEssentia’s occupational injury indicators is lower. The company does not have any occupational injuries caused by the number of deaths, severe occupational injuries, and occupational diseases. Even when an occupational disaster occurs, we will investigate and follow-up improvement measures following the “ On-Site Medical Staff Service Contract.” In 2020, we held a total of 3 emergency response drills. The topics of the drills included self-defense fire drills, toxic chemical incident response drills, and biosafety emergency response drills. The total number of participants was 73. In the future, we expect to establish an Occupational Safety and Health Committee in 2021 and introduce the ISO 45001 Occupational Health and Safety Management System in 2022 to conduct a systematic safety risk assessment in production processes and experimental operations.

2020 occupational safety and health employee training			
Training topic		Number of occurrences	Number of participants
Internal training	General safety, health, and hazard awareness training for new employees	7	24
	Annual self-defense firefighting team training	2	72
	Emergency response drill for toxic chemical substances	2	16
	Occupational health and safety four prevention program	1	68
	Logistics center safety and health code	4	5
External training	On-job safety and health training for operators of hazardous equipment	2	7
	On-job safety and health training for hazardous work supervisors	2	5
	On-job safety and health training for operators of special operations	4	4
	General training for professional responders of poisonous disasters in Central Taiwan Science Park	2	3
	Northern Joint Defense Organization Training Seminar	1	1
Total		27	205

Note: The data in this table cover Taiwan headquarters and subsidiary Panco Healthcare.

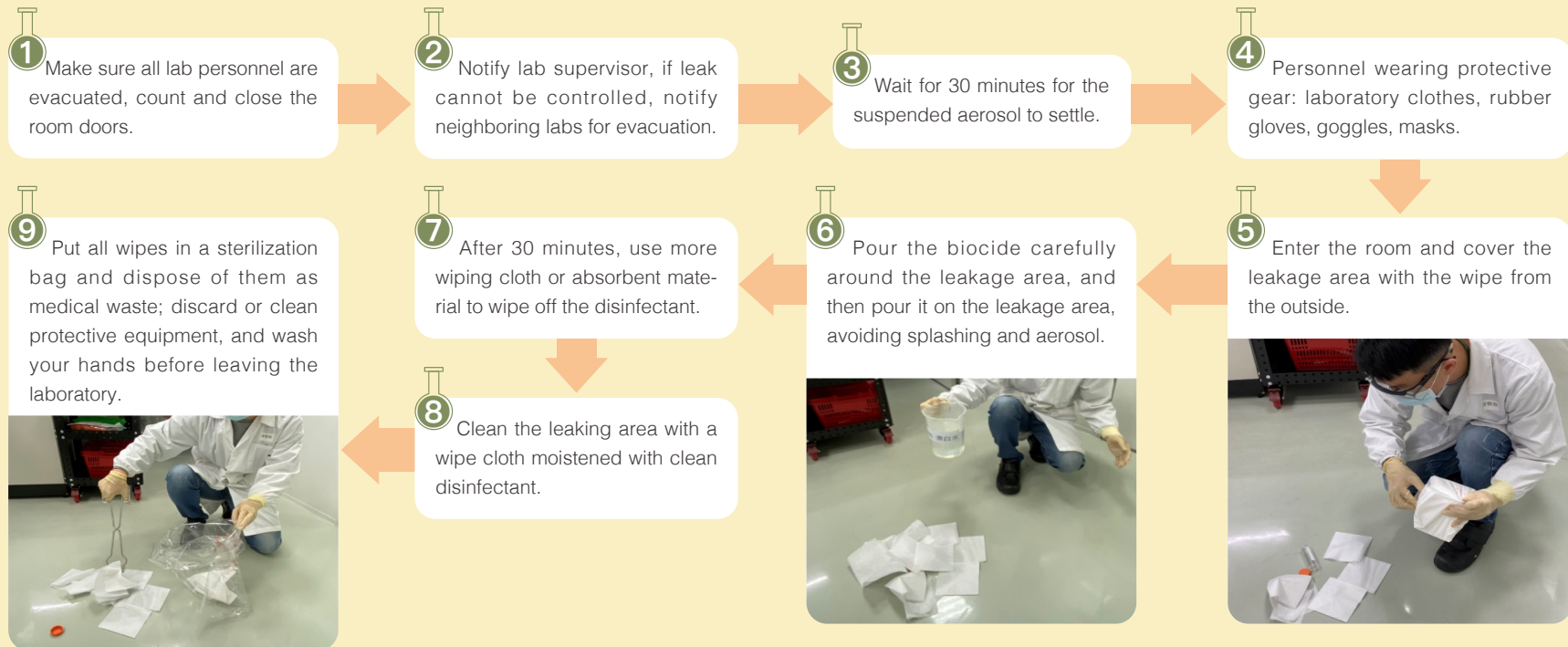
Example

A confirmed case of biosafety response drill

Rehearsal scenario setting: standard strains are overturned in the laboratory.

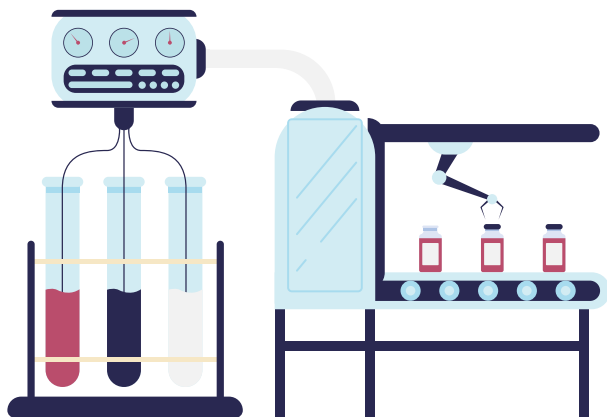
Participants: A total of 10 colleagues from related units of the Taichung manufacturing plant.

Drill process:



Contractor safety management

Regarding the safety of contractors entering the Company's factory, management mechanisms, and management measures are established for the pre-construction, pre-entry and construction period to ensure the safety of the Company's colleagues and contractors. In 2020, PharmaEssentia and Panco Healthcare did not have any occupational injury accidents by contractors in the Company's workplace, nor did they have any recordable number of occupational disease cases. In the future, we will continue to ensure the safety of our contractors, protect their rights and promote a safe and secure working environment.



Before construction

- The “Contractor’s Safety, Health and Environmental Protection Letter of Commitment” and the “Contractor In-plant Letter of Declaration” must be signed by the contractors and sent back to the Company.
- Submit 6 hours of safety and health training certificate.
- Retained by the Company’s Environmental Health and Safety Department



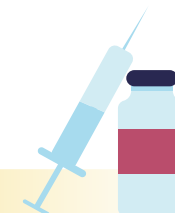
Before entering the factory

- Arrange for the contractor to receive pre-production safety and health training.
- The contracts must sign the “Notification of Workplace Environment and Hazardous Factors”.



During construction

- The engineering unit must ensure the contractors comply with the requirements stated in the “Regulations for Contractor Environmental, Safety and Health Management.”
- In case of special operations, a training certificate must be attached.
- Environmental safety unit conducts spot checks. In case of safety concerns, construction work should be suspended immediately.



Chapter 5

Environmental Impacts

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Chapter 5

Environmental Impacts



Relevant Material Topics



Waste management



Toxic chemicals management

Relevant stakeholders



Government agencies

Summary of Chapter 5

Highlights of 2020

This chapter aims to explain the impact of PharmaEssentia on the environment and related management actions. Because of the climate emergency faced by all human beings, we analyze greenhouse gas emissions and air pollution emissions statistics, including our energy consumption and carbon emission trends, unit conversion comparison trends, and emission intensity statistics, in response to the climate emergency faced by all of humanity. It is also expected to implement ISO 14064-1: 2018 greenhouse gas inventory verification in 2021. Carbon reduction targets are set through an inventory of emissions data. There have been no violations of environmental regulations or toxic chemical leaks for waste management and toxic chemical management. We expect to implement ISO 14001:

2015 environmental management system and ISO 45001: 2018 occupational health and safety management system in 2022, using the concept of life cycle assessment to reduce the environmental load and impact of waste generation and the risk of occupational hazards caused by chemical operators. Finally, we review the annual water management situation in light of the shared global crisis of water scarcity. In addition to daily advocate the importance of water conservation to employees, PharmaEssentia also recycles process water to cooling towers for reuse. In 2020, the amount of water recycled and reused will reach 7.7 million liters. PharmaEssentia is committed to fulfilling its role as a corporate citizen to ensure that our operations can achieve the goal of a friendly environment.

Performance highlights

Zero penalty

No incidents of violation of environmental laws and regulations

Zero leakage

Toxic substances are properly managed without accidental leakage

Zero-emission

Ozone Depleting Substances (ODS)

Air pollutant emissions are lower than the legal value.

7.7 million liters of processed water are recycled and reused.

Introduction of the Management System

It is expected to implement ISO 14001:2015 Environmental Management System and ISO 45001 2018 Occupational Health and Safety Management System respectively by 2022.

5-1

Climate Change Mitigation Strategy

The Fifth Assessment Report (AR5) in 2014 of the Intergovernmental Panel on Climate Change (IPCC) states that the warming effect of global warming will be significantly exacerbated the frequency and intensity of extreme weather in future climate scenarios. Accordingly, the United Nations has repeatedly called on governments of all countries to reduce greenhouse gas emissions to mitigate global warming. On the other hand, it is actively responding to and formulating adaptation actions for climate adaptation. Therefore, energy management and Greenhouse Gases (GHGs) emissions have also become essential tasks for international companies to practice sustainable operations.



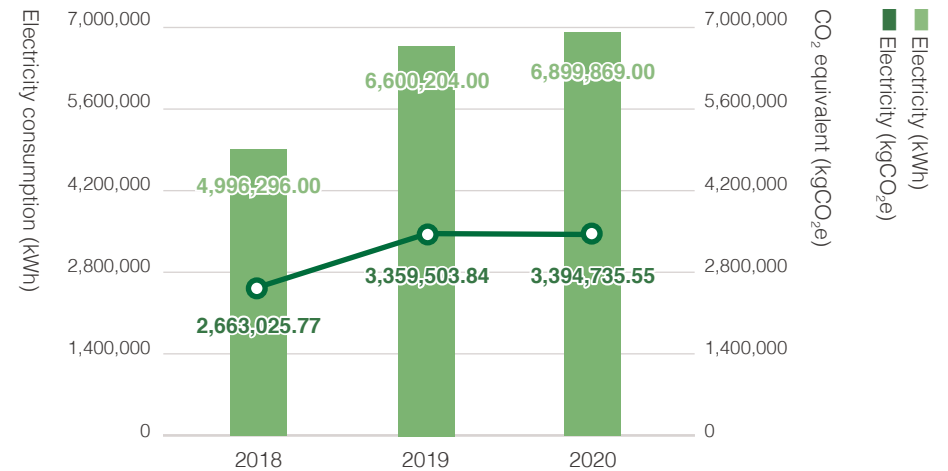
Statistics of GHGs emission

In September 2020, PharmaEssentia implemented the project of “ISO 14064-1:2018 Greenhouse Gas Inventory” and completed the implementation of the site survey, understanding the scope of the inventory and related equipment, as well as holding an inventory kick-off meeting and internal auditor education training with the participation of 16 internal colleagues. In 2021, we will complete identifying and quantifying greenhouse gas emission sources with a preliminary review of the recovery data. The greenhouse gas inventory verification is expected to be performed in 2021. We will also set carbon reduction targets in the future through the inventory of emission data. Further, we have realized the trend of disclosure of climate change globally, and thus we will take the “ Task Force on Climate-related Financial Disclosures, TCFD ” as a framework for disclosing the risks and opportunities of climate change.

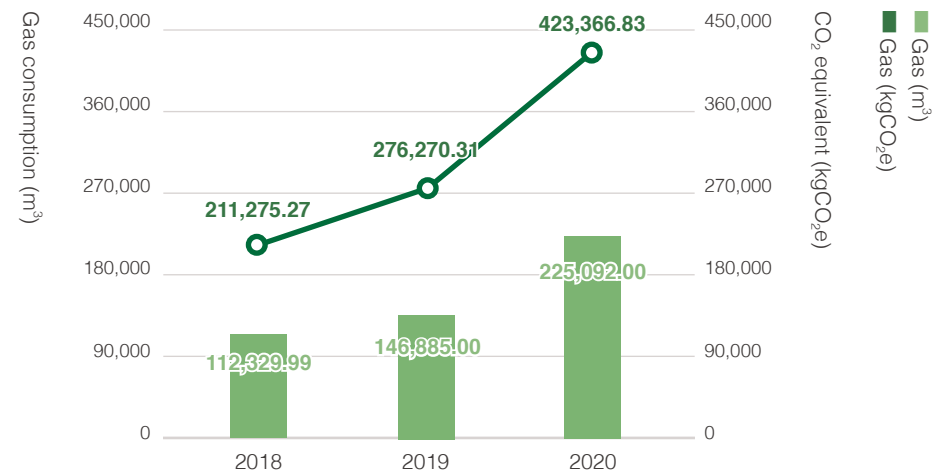
The Company’s energy consumption is divided into two main categories, namely purchased electricity and natural gas. As a pharmaceutical industry, it is required to comply with GMP regulations and maintain a certain level of cleanliness and quality control even during non-production periods, including fixed maintenance expenses such as boiler operation, process water, air conditioning, and environmental cleaning in the plant, which resulted in the total amount of primary electricity consumption and carbon emissions not being reduced. As the Company has not yet entered into global commercial mass production, the intensity of CO2 equivalent emissions per unit of product in 2020 will also be affected. We are committed to several energy-saving actions and regularly review the implementation results of purchasing and replacing equipment, appliances, saving electricity and water, and formulating improvement measures through tracking mechanisms and difference analysis. We will continue to work towards reducing the intensity of energy consumption and reducing the impact of our operations on the environment.

Energy consumption and greenhouse gas emission statistics for the past 3 years						
Type	Electricity		Natural Gas		Total	Emission intensity per unit product
Year	kWh	kgCO ₂ e	m ³	kgCO ₂ e	kgCO ₂ e	kgCO ₂ e/g
2018	4,996,296.00	2,663,025.77	112,329.00	211,275.27	2,874,301.04	79,051.18
2019	6,600,204.00	3,359,503.84	146,885.00	276,270.31	3,635,774.15	59,311.16
2020	6,899,869.00	3,394,735.55	225,092.00	423,366.83	3,818,102.38	88,751.80

Electricity use and greenhouse gas emissions in the past three years



Gas consumption and greenhouse gas emissions in the past three years



Note 1: Electricity emissions are calculated according to Article 28 of the Electricity Law (106.01.26), and the carbon dioxide equivalent coefficients announced by the Bureau of Energy, Ministry of Economic Affairs, are used to convert the carbon dioxide equivalent coefficients of electricity. The coefficients used for 2018 and 2019 are 0.533 and 0.509 kilograms of carbon dioxide equivalent (kgCO₂e) for 1 kWh of electricity. The coefficient for 2020 is the target value of 0.492 as estimated in the Executive Yuan Gazette, Vol. 24, No. 132, Economical Energy No. 10704603910.

Note 2: The GHG statistics method uses the "emission coefficient method," i.e., "activity data" is multiplied with the corresponding "emission coefficients," and then the various GHGs global warming potential (GWP) is converted into CO₂ emission equivalents.

Note 3: The greenhouse gas emission coefficient required for greenhouse gas emissions is based on the "Greenhouse Gas Emission Coefficient Management Table 6.0.4 Edition" announced by the Environmental Protection Administration, Executive Yuan, and use the GWP of various GHGs in the IPCC AR5 (2014) report as the basis for calculation.

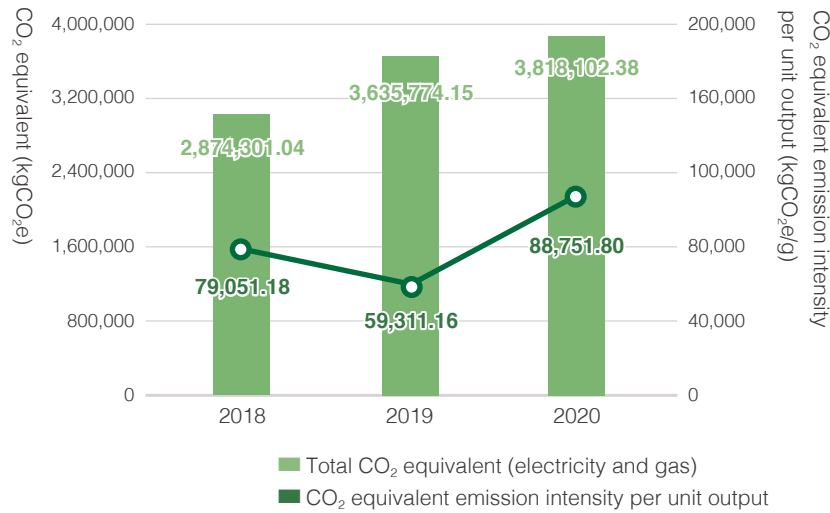
Note 4: The data for 2018 and 2019 do not include the subsidiary Panco Healthcare, in the 2020 data, Panco Healthcare only consumes purchased electricity, with a CO₂ equivalent of 20,644.32 kg-CO₂e, accounting for less than 1%, which does not affect the comparability of energy consumption and GHG emissions in the last three years.

Statistics of Air pollution

GRI 305-6

GRI 305-7

Statistics of carbon dioxide equivalent emission intensity per unit output in the past three years



Regarding the emission of air pollutants, as the Company uses boilers in the manufacturing process, the primary emission is the nitrogen oxides from the combustion of the boilers. The Company also does not use and emit ozone-depleting substances (ODS) regulated by the Montreal Protocol, nor do we emit any Persistent Organic Pollutants (POPs).

Information on major gas emissions affecting the environment in 2019 & 2020 (Unit: kg)

Air pollutants	Nitrogen oxides (NOx)	Sulfur oxides (SOx)	Volatile Organic Compounds (VOCs)	Hazardous Air Pollutants (HAP)	Particulate Matter (PM)
2019	649.00	102.00	10.00	8.00	8.00
2020	415.70	29.60	13.30	N/A	7.00

Note: Panco Healthcare does not emit any air pollutants in these items.



5-2

Waste management

Materiality Topic

Management approach on waste management

To effectively manage our waste, we review the detailed processes of waste generation, removal, treatment and recycling from a life-cycle perspective, and through a systematic waste management policy, we avoid the risk of improper handling that may lead to illegal concerns or pollution of the environment. We also actively assign our business executives to participate in external environmental seminars and regulatory presentations. In 2020, we sent our staff to seven external training sessions to keep abreast of various environmental regulations and the latest trends, so that we can effectively follow the changes in regulations and keep up with the trends when we think about and promote our actions to reduce emissions at source, adjust our process design, or improve the utilization of consumables. With that, we can reduce the waste of resources, reduce environmental pollution, and achieve the specific practice of friendly environment.

GRI 103-2 GRI 103-3



Policies

Internal Policy

Follow the “Environmental Safety and Health Policy” and “Waste Management Procedures.”

External Guidelines

Regulations for the Review of Business Waste Cleaning Plans



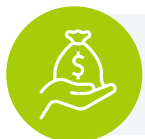
Commitments

Comply with environmental protection laws and regulations, and require manufacturers to implement waste flow control together to fulfill the commitment of being friendly to the environment.



Responsibilities

- The environmental friendly team is responsible for developing, planning and promoting waste management issues, and collaborating with R&D, environmental safety and production units to implement waste management responsibilities.
- Execution Center for Corporate Sustainability - Environmental Friendliness Taskforce



Resources invested

In 2020, the cost of business waste removal and disposal is about NT\$630,000, mainly NT\$330,000 for general waste and NT\$300,000 for hazardous waste, and a specialist is set up to handle them.



Goals and targets

2021 short-term goal

1. Continue to check the output of waste chemicals (including toxic substances) in 2020 and follow-up treatment procedures, submit to the environmental protection authority the amendment to the “Industrial Waste Cleanup Plan” and approval of the disposal of toxic substances, and the subsequent legal treatment of waste chemicals (including toxic substances) to avoid violating environmental protection laws and regulations.
2. In 2021, we will check the types of waste output, improve reusability and reduce waste output. The goal is to increase the recycling rate by 3 to 5% per year to reduce the impact on the environment.



Goals and targets

2022~2024 mid-term goal

- In 2022, we will introduce the ISO14001 environmental management system to strengthen the environmental management in the factory and incorporate the concept of life cycle assessment to reduce the burden and impact on the environment through PDCA and implement environmental protection obligations.

2025~ long-term goal

- Implement the ISO14001 environmental management system and follow the environmental assessment results and recommendations for improvement. For example, planning paper less or paperless activities, reducing paper demand or purchasing recycled paper



Mechanisms for evaluating the effectiveness of the management approach

Management assessment mechanism

- Internal audit: irregularly audit waste management companies every year, review the Company's internal waste classification and storage management process, and regularly evaluate the output intensity of waste per unit. The calculation method is based on "waste output (per tons)/product output (per grams)" as the evaluation standard.
- External audits: the Central Taiwan Science Park Administration conducts legal compliance audits on the "Business Waste Cleanup Plan," waste removal and disposal procedures, and waste storage sites.

2020 assessment result

- Auditing status: 3 audits of waste vendors and 4 audits of waste temporary storage areas are in compliance with regulations.
- Improvements: in order to meet the needs of process changes, we revised the "Waste Cleaning Plan" and completed the audit of the Central Taiwan Science Park Administration to improve four deficiencies. The Taichung plant commissioned a legal vendor to assist in the removal of waste chemicals (including toxic chemicals) in 2020, and after the environmental protection authority agreed to complete proper disposal of the waste, a copy was made available for inspection.



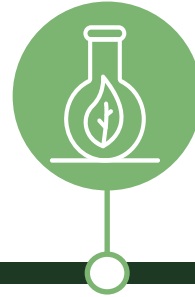
Short-, mid-, and long-term goals and actions for waste management



Short-term Goals

Waste disposal primary review

- Timely amendment of the “Waste Management Procedures.”
- Investigate the sources and material types of waste output in the factory, and reduce disposable materials or appliances based on their causes and characteristics.
- Increase the rate of waste reuse, comply with regulatory standards and implement recycling classification.
- We aim to reduce the impact on the environment by not increasing the amount of waste generated.



Mid-term Goals

Propose feasible solutions to strengthen management responsibilities

- Introduce ISO14001 environmental management system to re-examine our overall product design, manufacturing, distribution, consumption and waste production process through a life cycle perspective.
- Reinforce the waste management responsibilities of each unit.
- Seek alternative solutions for green products based on waste materials, increase the frequency of reuse, promote resource recycling, and reduce the total generated amount of waste.
- Strengthen the auditing of waste manufacturers and use compliance performance as the evaluation criterion for the selection of future manufacturers.



Long-term Goals

Introduce international standards to achieve waste reduction results

- Implementation of ISO14001 environmental management system.
- Promote paperless to strengthen digital communication within the Company.
- Purchase recycled paper, encourage double-sided printing and reuse recycled paper.

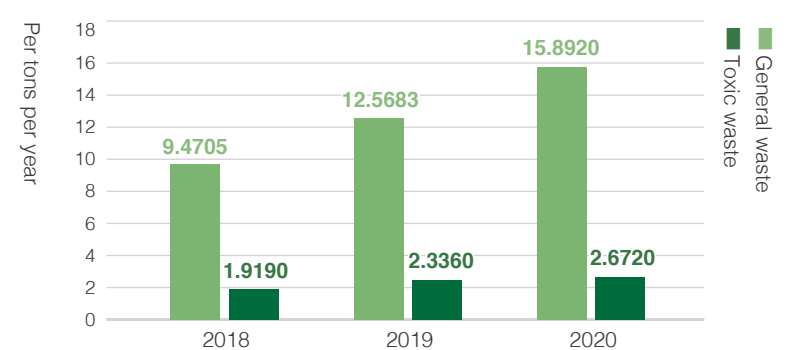
Waste classification and handling

GRI 306-2

The non-hazardous waste of PharmaEssentia is concentrated in the waste storage area according to the nature of the waste and then disposed of, while the hazardous waste is specially classified and sealed in specific containers with information such as name, weight, waste code and date, and then entrusted to qualified vendors for further processing. The biomedical-related and other infectious wastes are first subjected to high-temperature sterilization before being removed by qualified waste removal companies. Liquid wastes are mostly chemical wastes, which are then stored according to their flammability or acid-base value. When liquid wastes are collected, the handling personnel must pay attention to potential chemical reactions caused by the mixing of the liquid wastes, and at the same time, fill out the "Liquid waste mixture form" and paste it outside the liquid wastes container to facilitate subsequent processing. According to the waste treatment method, it can be divided into non-hazardous waste, general waste and resource recycling, and hazardous waste. For hazardous wastes, we assign the contractor to be responsible for cleaning and disposal. The disposal of waste is prioritized to the most environment-friendly reuse method, followed by resource recovery. If the wastes cannot be recycled and reused, they will undergo intermediate handling procedures, such as incineration or burial, or final disposal. The waste disposal companies contracted by the Company are legally registered class A licensed waste removal/processors regardless responsible for removal or final disposal. We also operate in a "tripartite checklist operation," which requires the completion of the process by the Company, the cleaning company, and the final treatment plant with a seal, and then finally reporting to the EPD official website to complete the process in order to control and manage the final flow of waste.

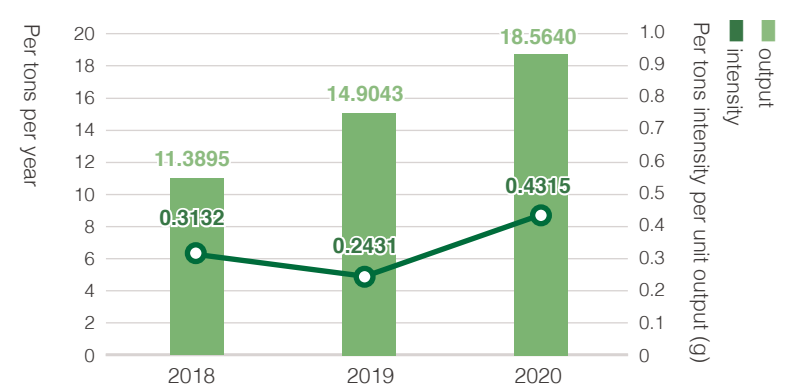
Hazardous waste				Non-hazardous waste		
Solid waste		Liquid waste		Solid waste		Liquid waste
Biomedical waste	Waste chemicals	Inorganic waste liquid	Organic waste liquid	Trash	Recycle	Organic waste liquid
Outsourcing (incineration)	Outsourcing (physical)	Outsourcing (physical)	Outsourcing (incineration)	Outsourcing (incineration)	Outsourced recycling (reuse)	Outsourcing (incineration)

Statistics of waste composition in the past 3 years



Note: The data for 2018 and 2019 do not include Panco Healthcare.

Statistics of waste intensity per unit output in the past 3 years



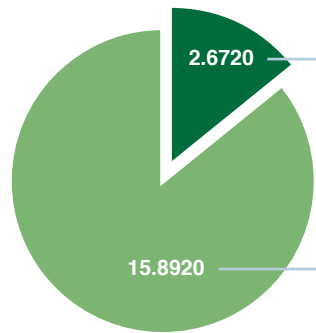
Note: The data for 2018 and 2019 do not include Panco Healthcare.

According to the statistics of waste output per unit of product in the past three years, it can be found that there is still room for the Company to continue to strengthen the reduction of the intensity of waste output. In the future, we will continue to reduce the amount of waste, improve the efficiency of unit output, and reduce the intensity of unit waste output as our goal, and follow short-, medium-, and long-term goals and action to refine management policies and implement management actions.



Classification of waste output by composition

GRI 306-3-5



Unit: Tons

- Nonhazardous waste
- Hazardous industrial waste

Hazardous waste

Unit: Tons

Disposal transfer (Note 1)	Direct disposal
-	2.6720

Note 1: There is no disposal and transfer volume of hazardous waste.

Nonhazardous waste

Unit: Tons

Disposal transfer (Note 2)	Direct disposal
2.6900	13.2020

Note 2: The disposal of non-hazardous waste is transferred from disposal in the form of off-site outsourcing and reuse.

Unit: Tons

Direct disposal of hazardous waste	Self-disposal on site	Off-site outsourcing disposal	Total
Incineration (with energy recovery)	-	-	-
Incineration (without energy recovery)	-	2.2700	2.2700
Heat treatment	-	0.0215	0.0215
Chemical treatment	-	0.3800	0.3800
Total	-	2.6720	2.6720

Unit: Tons

Direct disposal of nonhazardous waste	Self-disposal on site	Off-site outsourcing disposal	Total
Incineration (with energy recovery)	-	-	-
Incineration (without energy recovery)	-	13.2000	13.2000
Total	-	13.2000	13.2000

Note 3: There is no other disposal method for non-hazardous waste.

5-3

Toxic chemical substances management

Materiality Topic

Management approach on toxic chemical substances management

In the manufacturing process of pharmaceutical products, the EPA-listed “Toxic and Concerned Chemical Substances” are used, and the impact of these toxic chemicals is more significant than that of other chemicals. For the chemical toxicant management, the Company focuses on source management, and appropriate storage and usage. At the same time, implements written records of usage status to manage the flow of chemical toxicants and prevents toxicant pollution.

GRI 103-2 GRI 103-3



Policies

Internal Policy

Follow the “Environmental Safety and Health Policy” and “Chemical Hazard Management Procedure.”

External Guidelines

Toxic and Concerned Chemical Substances Control Act



Commitments

Comply with environmental laws and regulations, implement toxic chemical management to avoid disasters that cause environmental pollution or harm to human health.



Responsibilities

- The actual use, maintenance, management and operation of toxic chemicals are the responsibility of the research and development or use unit, while the rest are the joint responsibility of environmental safety, use and storage units for the management of toxic chemicals.
- Execution Center for Corporate Sustainability - Environmental Friendly team



Resources invested

In 2020, the cost of disposal of hazardous waste is about NT\$300,000, and the cost of purchasing additional contingency equipment is NT\$12,000, and the issue of waste management is handled by dedicated personnel. Approximately 10 manpower for toxic chemical substances disaster drills this year



Goals and targets

2021 short-term goal

- Set up emergency response personnel for toxic chemicals, implement the concepts of toxic chemical hazards and emergency response for toxic chemical operators (including units), assign personnel to participate in external training to obtain qualifications, and implement daily toxic chemical disaster response and drills.



Goals and targets

2022~2024 mid-term goal

1. Introduce ISO 45001 2018 occupational safety and health management system in 2022 to strengthen the awareness of chemical hazards (including toxic chemicals), risk assessment, and disaster emergency response management in the plant to reduce the risk of chemical operation to personnel.
2. For hazardous chemicals (including toxic chemicals), find substitute chemicals to replace or adopt low hazard chemicals to reduce the risk of chemical operation

2025~ long-term goal

Extend the use period of chemicals and reduce chemical waste by reducing 2~3% per year to achieve chemical waste reduction measures.



Mechanisms for evaluating the effectiveness of the management approach

Management assessment mechanism

- Taichung Environmental Protection Bureau visits the plant to check the implementation of toxic chemical operations.
- CSTA visits the plant to check chemical declaration and management.
- Taipei Environmental Protection Bureau conducts a toxic chemical operation audit at the Company's Taipei laboratory.

2020 assessment result

- No major violations

Classification and control of toxic and chemical substances

PharmaEssentia classifies toxic chemicals according to the definition of the Toxic and Concerned Chemical Substances Control Act, and stores the listed toxic chemicals in explosion-proof fume hood in the laboratory according to different categories. The Company's classification and control measures are as follows.



Figure 16: Fume hood for toxic chemical operations.



Figure 17: Explosion-proof fume hood for storage of toxic substances in tubes.

Toxic chemical disaster response drill

Category

Type 1 chemicals

Difficult to decompose material, meaning that it is not easy to decompose in the environment or due to bioaccumulation, bioconcentration, biotransformation and other effects, resulting in pollution of the environment or harmful to human health.

Type 2 chemicals

Chronic toxic substances, which have the effect of causing tumors, impaired fertility, malformations, mutations of genetic factors or other chronic diseases.

Type 3 chemicals

Acute toxic substance, the chemical substance will immediately endanger human health or biological life after exposure.

Type 4 chemicals

Endocrine disruptors or those who pollute the environment and endanger human health

Management procedures

Access control

Personnel access control



Chemical cabinet control

The chemical cabinets are locked and the key is managed by a delegated person.



Usage control

The user must fill in the usage form, and the environmental safety unit collects and reports the monthly operation amount on a monthly basis.



In order to maintain the safety of employees, PharmaEssentia has also formulated emergency response procedures for toxicant leakage and subsequent containment. In the event of an emergency incident of toxicant leakage in a major factory of the Taichung plant, employees must follow the notification procedures and first notify the environmental safety personnel in the plant and, at the same time, the environmental safety supervisor of the Central Taiwan Science Park and the top supervisor of the plant, and then initiate the in-plant Procedures for Emergency Responses for toxicant leakage. In addition to the emergency response procedures, we also have emergency response equipment in the laboratory, such as leak plugs, half-face gas masks, acid-proof gloves and acid-proof boots, etc., for employees to use in emergencies. A delegated person is in charge of the monthly safety level count of the emergency equipment. Every year, the Company also conducts toxic and chemical spill management disaster drills and biosafety drills from time to time to ensure that employees can respond immediately and quickly to reduce the impact of disasters and maintain workplace safety in the event of an emergency. In the future, in accordance with the Toxic and Concerned Chemical Substances Control Act, we will also set up professional response personnel for toxic and chemical substances in plants to take necessary protective, response and cleanup measures in the event of an accident, and to implement toxic and chemical disaster response operations and education and training for toxic and chemical substance operators in plants.

Emergency response exercise for toxic and chemical substances leakage

Exercise scenario setting: type 1 toxic chemical accidentally leaked during operation

Participants: a total of 16 colleagues from the relevant units of Taichung manufacturing plant

Drill response procedures:

1. Report

According to the notification procedure of the leakage of toxic substances in the plant, notify the environmental safety personnel in the plant, and inform the toxic substance response personnel to prepare emergency response equipment and support response, and to evacuate and control personnel outside the disaster site.



2. Special dressing

Before entering the site, responders should wear Class C protective clothing, filter canister type gas mask, chemical protective gloves, chemical protective boots and other equipment.



3. Leak stoppage processing

1. After the responding personnel enter the site they should check and confirm that the operator has completed the decontamination and ask the enforcement personnel to retreat and leave.
2. Response personnel perform disaster control operations.
3. After the spilled solution is cleaned, put it into the chemical waste bin together with the collection bag and the cleaning and absorbing cotton, and confirm whether the cleaning of the site is completed.



4. Response personnel remove pollutants

1. Before evacuating the site, the responding personnel should enter the emergency shower room to decontaminate and put the protective clothing into the chemical waste bin before evacuating.
2. The responding personnel shall inform the environmental safety personnel that the disaster site has been decontaminated, and then the environmental safety personnel shall report to the plant commander that the disaster condition has been lifted.
3. Follow-up disposal of waste in accordance with hazardous waste treatment procedures.



5-4

Water resources management

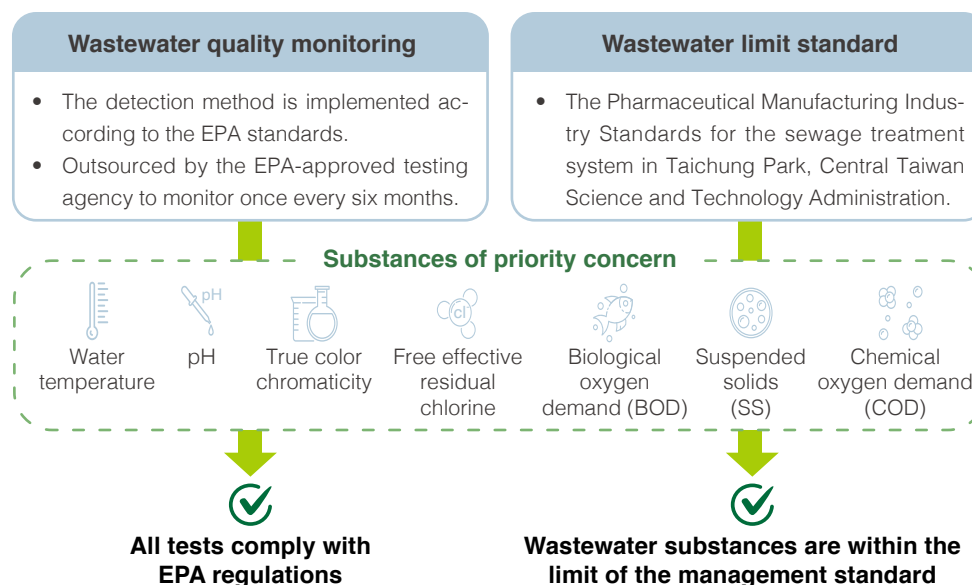
GRI 303-3~5

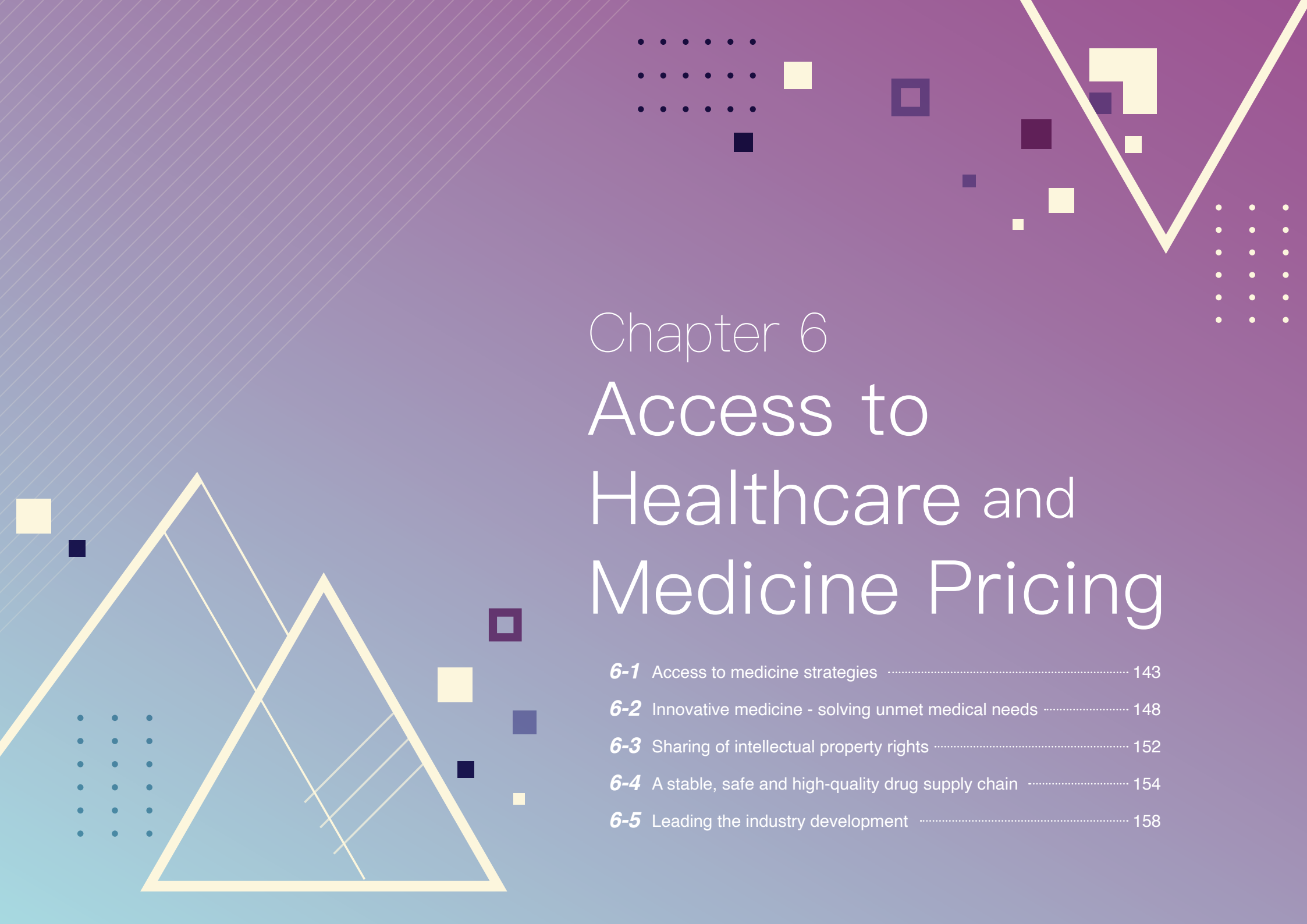
For eight consecutive years, the water crisis has been listed as one of the greatest risks facing the world in the World Economic Forum (WEF) Risk Report. The issue of water management is also the sixth of the United Nations' Sustainable Development Goals (SDG 6), which aims to improve the quality of life by improving access to clean water and sanitation within 10 years. Although the nature of our main pharmaceutical research and development business and the manufacturing process do not consume a large amount of water resources, we do take measures to conserve water resources. In terms of the Taichung manufacturing plant, which accounts for the largest water consumption, discharge and water consumption of the Company, according to the statistics in 2020, the annual water consumption of the Taichung plant only accounts for 0.016% of the Taichung Park of the Central Science Park, and the annual drainage volume is About 0.031%. It shows that the Company's use of water resources does not pose a significant impact on the Science Park where it operates. The total water consumption of the Taipei headquarter and Panco Healthcare, is approximately 1 million liters in 2020, with drainage mainly for domestic use and consumption mainly for drinking water. Since the administrative office area does not have a plant process, there is no precise statistical data on drainage and water consumption.

The water quality monitoring frequency of the discharge water of Taichung plant is once every six months, and the testing method is carried out according to the specification of EPA, and the external testing agency is approved by EPA. The discharged water is properly treated at the wastewater treatment plant in the Taichung Science Park of the Central Taiwan Science and Technology Administration (CSTA) and discharged in accordance with the standards for the pharmaceutical manufacturing industry under the CSTA Taichung Science Park wastewater treatment system. The quality of water discharged by the Company in 2020 was within the discharge control items and limits, and there was no significant environmental pollution. In terms of recycling water resources, the Taichung manufacturing plant is recycling the reverse osmosis brine and wastewater from the manufacturing process to the cooling water tower in the air conditioning system, thus enhancing the efficiency of water recycling. The recycle amount of water was 7.7 million liters in 2020.

Statistics of water withdrawal, discharge and consumption of the Taichung plant for the past 2 years (unit: million liters)		
	2019	2020
Water withdrawal	15.91	15.64
Water discharge	9.08	9.46
Water consumption	6.83	6.18

Note: The Company's water sources are fresh water from third-party (total dissolved solids is less than or equal to 1,000 mg/L). Wastewater is also discharged through a third-party, the Sewage Treatment Plant of the Central Taiwan Science Park. The Company's wastewater discharged is non-fresh water (total dissolved solids is greater than 1,000 mg/L).





Chapter 6

Access to Healthcare and Medicine Pricing

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Chapter 6

Access to Healthcare and Medicine Pricing

Summary of Chapter 6

Highlights of 2020



The mission of PharmaEssentia is to provide holistic, R&D, innovative and breakthrough drugs to patients in need to solve their suffering and improve their lives and health. We are also committed to the development of new drugs and will continue to promote “accessibility” to new medicines for patients around the world through our Access to Medicines Strategy Program: providing access to medicines that treat disease needs and are available through legal and safe channels. “Affordability”: making medicines available at reasonable, fair and affordable prices. “Availability”: helping patients in economically disadvantaged countries to access the medicines they need and reduce access disparities. We maximize patient coverage in global markets to promote patient health and well-being.

Relevant material topics



Access to medicine

Relevant stakeholders



Investors



Healthcare providers



Patients



NPOs/NGOs



Performance highlights

Disease worsening index reduced by 30 percent

Data from a 5-year clinical trial found that after 5 years of treatment with Ropeginterferon alfa-2b (P1101) in patients with PV, the mutation index for disease progression decreased from 37.3% to 7.3%.

Accumulated certification of orphan drugs for PV in 2 countries

Ropeginterferon alfa-2b (P1101) has received multiple orphan drug approvals for hemopoietic disorders from the U.S. authorities, and in 2020, an orphan drug approval for the treatment of Polycythemia Vera (PV) in South Korea was added.

Patient education and care

Launched the Patient Assistant Program based on the pharmaceutical marketing ethical standards of various countries.
Established [“MPNiCare” Platform](#).

Ropeginterferon alfa-2b (P1101) benefits more than 1,500 PV patients

BESREMI® is now available in 18 countries in Europe.
Accumulated more than 19 clinical trials worldwide.
Benefits more than 1,500 patients.

Reliable and stable drug supply chain

For the Asian market, filling and packaging is done by our factories located in Taiwan, while for European and American markets, these are entrusted to local qualified manufacturers. No incident related to product quality that must be reported in the year 2020.

Strengthening the medical system and increasing shared value

First to initiate and sponsor the “MPN ASIA (an International Conference on Myeloproliferative Neoplasms)” to promote the exchange of the latest treatment views between experts, scholars and clinicians in Asia, as well as inviting experts to share clinical experience practices from Europe and the US.

6-1

Access to medicine strategies

SASB HC-BP-240a.1

Materiality Topic

Access to medicine management approach

At PharmaEssentia, we always pursue cutting-edge science in order to translate innovative science into medical solutions that bring value to patients. We hope to become a biopharmaceutical innovation company that brings health and well-being to all of humanity through our successful new drug products that address the suffering of patients. Therefore, access to medicine is the most important issue in our social engagement. We take the enhancement of “accessibility,” “affordability” and “availability” as our core concept and commitment. In addition, we follow the framework of Access to Medicine Index 2018 to formulate strategies and guidelines. The aim is to reduce the gap between patients’ access to medicine, so that patients can obtain the drugs they need in a reasonable, affordable, correct and easy way, and become a sustainable enterprise that patients can trust through our social influence. And through the access to medicine management policy closely integrated with the business development strategy, while practicing the Company’s business opportunities, it also creates shared value for patients. We also expect to achieve the UN SDG Goal 3 “Health and well-being” by 2030 with our corporate efforts.

Corporate philosophy and strategy

Our new pharmaceutical products are designed to address the suffering of patients and promote the health and well-being of all people to achieve UN SDG Goal 3.



Core concept and commitment



Increase accessibility

Provide drugs that treat disease needs and are available through legal and safe channels.



Ensure affordability

Responsible, reasonable and fair pricing mechanism.



Increase availability

Help patients in economically disadvantaged countries access the medicines they need and reduce the disparity in access the medicine.

Strategic guidelines and access to medicine plans

Governance of access to medicine

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).

R&D

Innovative medicine - solving unmet disease needs

- Creating value through innovation.
- Modification of existing drugs to reduce the risk of developing new drugs.
- Utilizing technology platform to effectively develop diverse products.
- Launching multi-country and multi-center clinical trials.
- Collaborations with foreign universities.
- Providing Compassionate Use to patients not able to participate in clinical trials in Taiwan.

Product delivery

Responsible and transparent intellectual property right management

- Promising to take into consideration the access to medicine of patients in low income countries (LICs) and least developed countries (LDCs) when utilizing and applying for patents to ensure the treatment needs of patients.
- Through licensing-in and licensing-out, clinical trials and post-market sales of new drugs are carried out all over the world.

Stable, safe and high-quality drug supply chain

- Short- and mid-term drug license application plans around the world.
- Fair, reasonable and affordable drug pricing.
- Ensuring the safety, stability and high quality of the drug supply chain.
 - Short- and mid-term drug license application plans.
 - Fair reasonable and affordable drug pricing.
 - Ensure safe, stable and timely delivery of medicines to meet patients' needs.
 - Patient education and care.

Leading the industry development

- Sponsoring the conference on Myeloproliferative Neoplasms Asia (MPN Asia).
- Cooperating with value chain partners to strengthen social influence on the local biotechnology and pharmaceutical industry.
- Promote initiatives on issues related to access to medicine.



Management approach on access to medicine

GRI 103-2 GRI 103-3 GRI 203-1

The Company will contribute to the improvement of human health by providing innovative and reliable pharmaceutical products, providing for unmet medical needs, and seeking advances in medical technology. For some poor areas, the health care system is inadequate and new medical drugs and technologies are not easily accessible. We will also strive to facilitate access to medicine in these regions, and therefore our access management mechanism is guided by a key policy of “discovering, developing and delivering innovative medicines to patients” and reflects our commitment to accessibility, affordability and availability. When managing the Company’s business practices, we are also committed to complying with the highest ethical standards and all applicable laws, regulations, industry standards, and company policies and procedures. Our access to medicine management policy is closely related to the value chain of the product life cycle and is implemented in the management of issues at each stage, as follows.



Policies

Value chain	Description
Innovative drugs discovery	The Company aims to develop new drug needs that have not been met with its own technology, and strives to protect the safety of patients' access to medicine in an ethical and ethical manner for the human clinical trial process. We also prescribed the policies and SOP of Compassionate Use. For more details, please refer to Chapter 1, Section 1.3 major issue “R&D of new biopharmaceuticals.”
Preclinical study	
Clinical trial	
Manufacturing and production	In order to ensure that we can establish a stable, safe, and high-quality drug supply chain for patients, we use the highest quality standards in terms of manufacturing process, quality control and drug safety monitoring, and strictly follow the international standard GxP. For more details, please refer to Chapter 2, Section 2.3 “Compliance and Business Ethics” and the management approaches of major issues in Chapter 3.
Innovative drugs registration	In order to comply with the local regulatory requirements related to pharmaceuticals in various countries and to ensure the compliance requirements at the stage of marketing application, please refer to Chapter 2, Section 2.2. “Compliance and Business Ethics” major issues management policy. In addition, we expect to complete our pricing policy in 2021, as we need to consider the pricing mechanism of each country’s market during the listing application stage.
Marketing and sales	The Company complies with the ethical standards of the WHO and other countries in the pharmaceutical industry, which can be found in Chapter 2, Section 2.3, “Compliance and Business Ethics.”



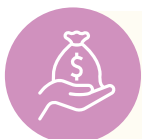
Commitments

- Use our new drug products to solve the suffering of patients and promote the health and well-being of all mankind.
- Accessibility: provide drugs that treat disease needs and are available through legal and safe channels.
- Affordability: responsible, reasonable and fair pricing mechanisms.
- Availability: make medicines available to patients in economically disadvantaged countries.



Responsibilities

- Currently, the Board of Directors and the senior management team of each subsidiary act as issue managers and implement access to medicine governance within the current system in conjunction with the business strategy. The Company has entered the commercialization stage and will consider the proposed access to medicine policy in the future.
- Execution Center for Corporate Sustainability - Access to Medicine Team



Resources invested

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 major issue in each section. In 2020, R&D expenses amounted to NT\$922 million and marketing expenses amounted to NT\$379 million.



Goals and targets

Our management goals

According to the three approaches of Access to Medicine Index drug use strategy guidelines: access to medicine management, R&D and product delivery. Our Company will leverage our strengths to contribute to the improvement of global health with our technology and expertise, and is committed to following the 5 major directions of access to medicine strategy:

1. Enhance the management strategies of drug accessibility.
2. Address unmet disease need with innovative medicines.
3. Responsible and transparent intellectual property right management
4. Provide stable and safe medicines.
5. Lead the industrial development to enhance the local capabilities.

2021 Short-term goal

1. Obtain Koreans medicament license marketing approval.
2. Complete a reasonable and fair internal management policy for drug pricing to achieve global operational goals.
3. Establish access to medicine policy.
4. 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), the American Society of Hematology (ASH).
5. 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.
6. 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 at the right time.
7. Address unmet disease needs through innovative medicines such as value creation through innovation, access to medicine programs that integrate global pipelines, initiation of multi-country, multi-center clinical trials, planning of short- to mid-term worldwide medicament license programs, transnational industry collaborations, and the provision of compassionate care for patients not enrolled in clinical trials in Taiwan.



Goals and targets

2022~2024 Mid-term goal

1. Obtain marketing approval for Ropeginterferon alfa-2b (P1101) for the treatment of PV in the U.S., other Asian countries (to expand and develop the use of the drug in Southeast Asia), and Central and South American countries.
2. 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.
3. Establish medicine life cycle management plan.
4. Lead the industry development.
5. Cooperate with value chain partners to strengthen social influence on the local biotechnology and pharmaceutical industry.
6. Promote initiatives on issues related to access to medicine.

2025~ Long-term goal

1. The goal is to accelerate medicament licenses in all countries by 2025 and to integrate the Company's ability to pay patients in developing or low- and middle-income countries with a high prevalence of new drug indications into its drug pricing strategy using reasonable and fair drug pricing principles.
 - Promote Ropeginterferon alfa-2b (P1101) to enter Eastern Europe, Central Asia, and even some African markets, and apply for a medicament license for PV to provide early access to patients in need.
 - Enter Southeast Asia, Central and South America, Eastern Europe, Central Asia, and even some African markets to apply for medicament licenses to market ET.
2. Responsible and transparent intellectual property right management
 - Promise to take into consideration the access to medicine of patients in low income countries (LICs) and least developed countries (LDCs) 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.



Mechanisms for evaluating the effectiveness of the management approach

Management assessment mechanism

- 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, pricing and international marketing compliance.
- Such as the Declaration of Helsinki, ICH GCP, GXP standard specifications, WHO and national pharmaceutical marketing ethics standards, at this stage follow the Company's Compassionate Use Policy, internal control rules and standard operating procedures.

2020 assessment result

- BESREMI[®] has been successfully licensed for sale in 18 countries in Europe and 1 country in West Asia.
- Completed supply chain build-out for commercial use in Taiwan and Hong Kong.
- In 2020, we obtained medicament license in Taiwan and completed drug pricing evaluation reports and submitted applications for drug prices.
- In 2020, the compassionate care program benefited 38 patients with MPN in Taiwan, and clinicians published this clinical experience in medical journals to promote the exchange of industry information.
- In 2020, the Company approved the implementation of a project for the importation of MPN-related diseases in Hong Kong, which is expected to be implemented in 2021.

6-2

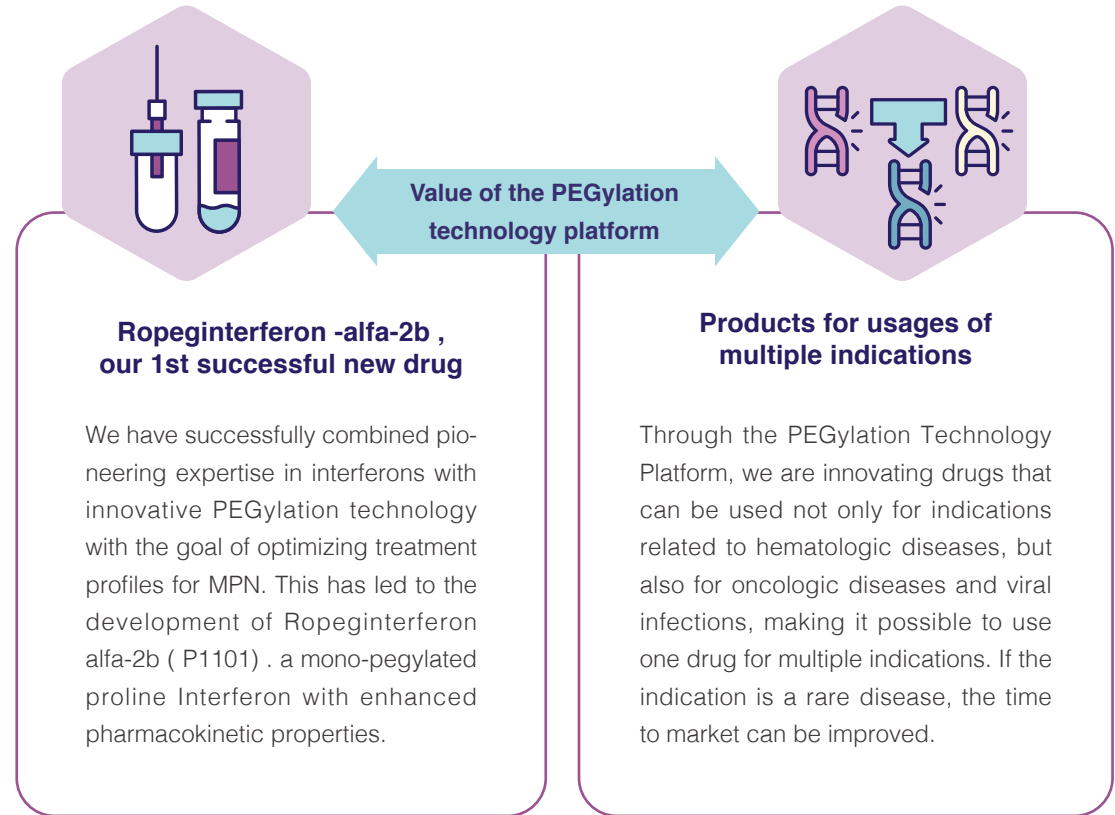
Innovative medicine - solving unmet medical needs

SASB HC-BP-240a.1



Creating value through innovation

On average, it takes 10 to 15 years to develop a new drug from the selection of a topic, technical research, clinical trials to market. During this long development process, a drug development company must not only invest heavily in R&D and recruit scientific expertise, but also have the patience and perseverance to keep trying and pursuing breakthroughs, and must even be able to bear the potential risks associated with the failure of new drug development, being ahead of competitors, or intellectual property rights, and persevere until the day of success. Patients, their families and friends, insurance companies and health care providers are all looking forward to the successful introduction of new drugs that will reduce the suffering of patients, provide better treatment options and reduce the cost of health care. In view of this, we have developed our own “PEGylation Technology Platform” to improve our existing drugs and have also successfully developed a new generation of PEG-based long-acting alpha interferon drugs to reduce the risks that the Company has to bear. Moreover, this innovative drug has the characteristics of one drug for multiple indications. Compared with other new drug companies, it is also the most competitive advantage. It can be used not only for the treatment of blood disease-related indications, but also for tumor diseases and viral infections. It is exactly where we create the access to medicine value of for patients.



Improvement of existing drugs to reduce the risk of developing new drug

Ropeginterferon alfa-2b (P1101)

5-year clinical trial research data results

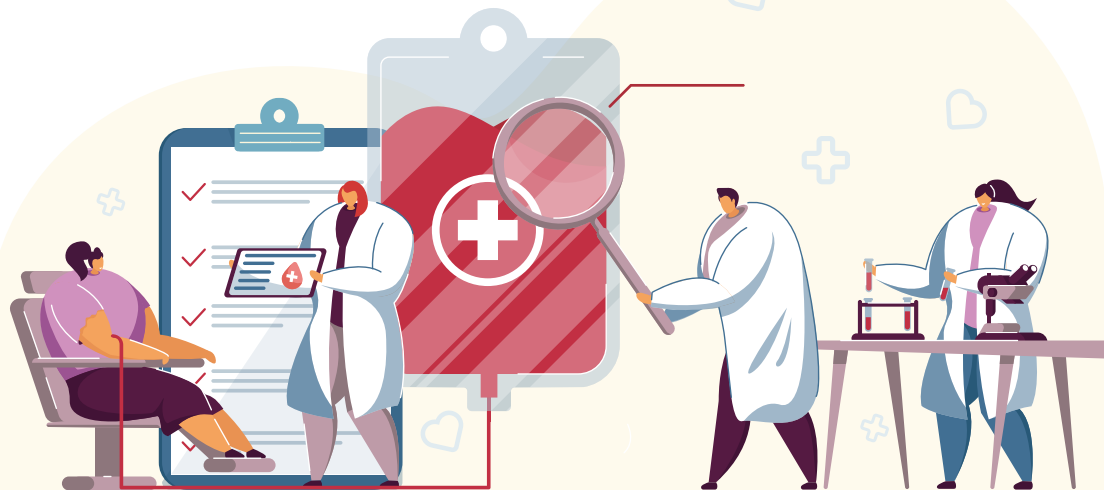
Nearly 70% of patients have a reduced risk of disease progression

69.1% of patients had improved mutation status, and the mutation index representing disease progression decreased from 37.3% to 7.3%.

Nearly 60% of patients reached a complete response

58.5% of patients achieved complete response without bleeding.

MPN are blood cancers, which are chronic diseases. Patients will experience progressive deterioration of the disease over time after suffering from cancer. It is recognized as a rare disease in some countries around the world and there has been a serious and unmet medical need. Regarding PV, which is one of the field of MPN, we have developed a new generation of PEG-interferon alfa-2b (P1101), a long-acting alpha interferon drug, based on our PEGylation platform, with significant results in the treatment of this disease. Our partner AOP Orphan used our Ropeginterferon alfa-2b (P1101) for the treatment of PV in a 5-year clinical study and found that more than half of the patients achieved complete response: maintaining normal blood volume ratio and gene mutation index reduce. The results of this study were also published at the 62nd American Society of Hematology (ASH) in 2020, and received enthusiastic responses from experts in related fields. They unanimously praised Ropeginterferon alfa-2b (P1101) for the treatment of PV. The long-term clinical trial results of PV are sufficient to confirm the research results of this innovative interferon drug and its potential to benefit the patient population. We also believe that in the foreseeable future, Ropeginterferon alfa-2b (P1101) will be able to gradually meet the demand for treatment of PV and even expand to other MPN diseases such as ET and PMF, providing patients around the world. We are committed to bringing health and well-being to patients with this disease by eliminating the pain and suffering caused by the access to medicine gap.



Utilizing technology platform to effectively develop diverse products

SASB HC-BP-000.B

Designation of orphan drug for Polycythemia Vera (PV) in the US and South Korea

One drug for multiple indications

Collaborations with Foreign Universities - Enhancing local R&D and clinical trial ability

Following the approval of Ropeginterferon alfa-2b (P1101) as an orphan drug by the U.S. authorities, in 2020, our Korean subsidiary actively communicated with the authorities and presented literature demonstrating the efficacy of Ropeginterferon alfa-2b (P1101) and its extremely low side effects and high patient tolerance for the treatment of PV. We received Orphan Drug Designation (ODD) approval for Ropeginterferon alfa-2b (P1101) for the treatment of PV from Ministry of Food and Drug Safety (MFDS). With this orphan drug certification, Ropeginterferon alfa-2b (P1101) did not require a separate bridging clinical trial in South Korea, and was exempted from the time and cost of conducting clinical trials in South Korea. We can also apply to the MFDS for an accelerated review, including conditional approval of the drug certificate and priority review. We also passed the GMP audit by the Korean MFDS competent authority in early 2021. We believe that after mid-2021, we will be able to bring our products into the Korean rare disease market, becoming the first approved treatment for PV in Korea clinical medicine. It is expected to bring better treatment plans to approximately 5,000 local disease patients.

Ropeginterferon alfa-2b (P1101) can be used not only for indications related to hematologic diseases, but also for neoplastic diseases and hepatitis viral infection disease. This drug can be used for multiple indications. It will help the Company reduce the R&D costs, resources and risks we face for various diseases, and provide our successful, effective, safe, and high-quality medicines for patients with various indications. We have also initiated multi-country and multi-center clinical trials globally. At present, our Company has simultaneously promoted more than 19 clinical trials, benefiting more than 1,500 patients in total. In addition, through the cooperation between Taiwan and Japan, we have a deeper understanding of the disease needs of the public health system in various regions. Based on the long-accumulated knowledge and insights of related diseases of external academic institutions, as well as our ability in the latest and most cutting-edge technology and skills, we can jointly implement the medicine access plans required by different diseases in different regions. In the future, we will also continue to accelerate access to medicine for patients around the world to fulfill our commitment.

2018 2019 2020 2021

Since 2018, we had been collaborating with domestic universities and research programs. The main focus was on the development and application of new nephrology drugs. The project was completed in the second quarter of 2020, with a total investment of over NT\$1 million in this industry-academia collaboration project.

Starting in 2019, we had been sponsoring domestic medical centers and Japanese academic institutions to conduct related viral hepatitis research programs. The project was completed by the end of 2020, with a total investment of over NT\$1 million in research expenditures.

Collaborated with domestic universities to research specific cancer drugs starting in 2019, and continue to receive support from government research programs through 2021.

Ropeginterferon alfa-2b (P1101) in Taiwan's Compassionate Use - benefit the patients

38

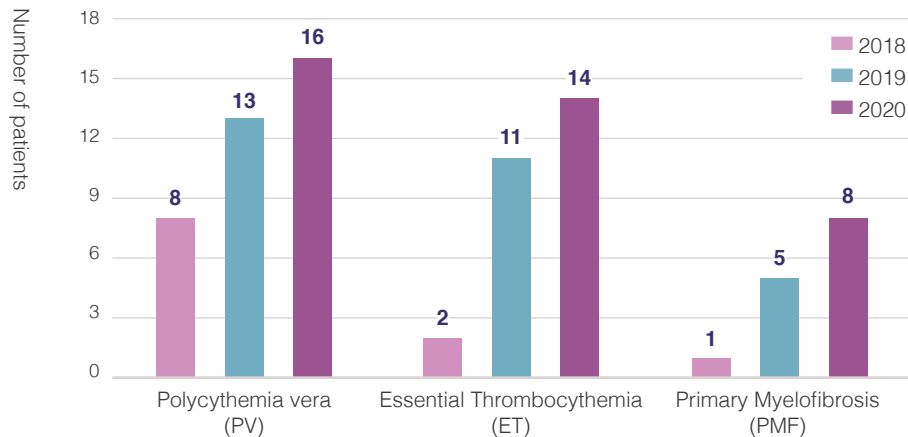
2020 approved compassionate use cases

30%+

Increase in the number of 2020 Compassionate Use cases compared to that of the previous year

Compassionate Use is the use of a new, under-trial, never-been-approved drug, which has been scientifically developed, in the treatment of patients in critical or serious condition who lack any alternative medicines, or have no response after all available medications, experience relapse, or have contraindications. Take Taiwan as an example. Starting in 2017, with the application submitted by the physicians and patients and approval from TFDA, Ropeginterferon alfa-2b (P1101), which was then a new drug under the clinical trial stage, served as the Compassionate Use drug for the treatment of PMF, PV, and ET. The total number of approved cases before the launch in Taiwan in 2020 was 38 cases. The Company will continue to promote policies and implement standard operating procedures for the provision of compassionate use medicines.

Chart of Compassionate Use patients in Taiwan



6-3

Sharing of intellectual property rights

SASB HC-BP-240a.1

Intellectual property rights of the access to medicine commitment



The Company promises to take into consideration the access to medicine of patients in least developed countries (LDCs) and low income countries (LICs) when utilizing and applying for patents to ensure the treatment needs of patients.

New drug development companies must bear the costs and risks of R&D over a long period of time. Therefore, appropriate patent protection and management can give new drug companies enough time to recover their R&D expenses, and it is also an important incentive for new drug development companies to invest in R&D of new drugs. The filing and maintenance of new drug patents is the starting point for the Company's efforts to promote global drug accessibility. After acquiring the patents in various countries, the Company will be able to allocate resources more effectively and implement strategic plans to enter the local market. In addition, the Company can also better educate local medical staff and patients based on the medicine access gap and demand situation of local market, local supply chains, and public health infrastructure to improve medicine accessibility and optimize patients' benefit.

We understand that in the least developed countries, the patients' access to medicine may still be restricted by the protection of intellectual property rights. Therefore, PharmaEssentia promises that we will give special consideration in some factors, in addition to the global prevalence of the indications of the new drugs, we take special consideration for the patients' access to medicine in the least developed countries and low income countries to ensure that the demand for drugs in non-developed countries can be fulfilled as in developed countries. In case of weighing between utilization of patents and humanitarian aid, PharmaEssentia will first prioritize the medical need of the patients, so that patients in need can obtain the required drugs at an affordable price and in a convenient manner.

In the future, we will also continue to conduct review and comparison on our self-developed and acquired intellectual property rights to understand the level of our new drug technology compared to our global counterparts, and update the connotation of lifecycle management of our pharmaceutical products, accordingly, outline the global intellectual property rights strategies. We will also regularly draw up intellectual property management plans that are integrated with our operations, and proactively disclose our patent policies, application and implementation status. This not only promotes the sharing of intellectual property rights, but also demonstrates our philosophy in sustainable management in accountability, integrity and transparent communication. As far as a new drug company is concerned, the key technologies from product development to commercialization are backed by the protection of intellectual property rights, which can not only enhance the Company's international competitive advantage, but also obtain economic benefits and feedback in the market. It will also provide the public with greater access to the content of new inventions, and to the implementation of public health protection, thereby contributing to the progress of society and the well-being of the public.



Patent licensing to maximize the value of intellectual property rights

PharmaEssentia attaches great importance to the transparency and sharing of intellectual property rights. Applying for a global patent is the most effective way for us to spread our exclusive knowledge and to promote technology progress. Based on our patent rights, we licensing-out patents and technologies to our partners based on our business development strategy, and we also cooperate with major foreign pharmaceutical companies to obtain licensing-in patents and technologies for development and subsequent commercialization. In the future, we will establish a systematic management mechanism for out-licensing and in-licensing management based on our own patents and technologies, in order to maximize the management efficiency and social value of intellectual property rights, to improve the accessibility of medicine.



- Our out-licensing strategic partner, AOP Orphan, is licensed to conduct clinical trials for Ropeginterferon alfa-2b (P1101) on the treatment of rare hematologic diseases in regions including Central Europe, the Commonwealth of Independent States, and the Middle East.
- AOP Orphan successfully obtained the EMA license in 2019, and immediately began the marketing and sales in the EU.

- ★ The Company obtains Athenex Inc. Tirbanibulin ointment authorized sales area.
- ✓ The Company obtains the authorized sales area of Oraxol[®], a cancer drug used by Athenex.

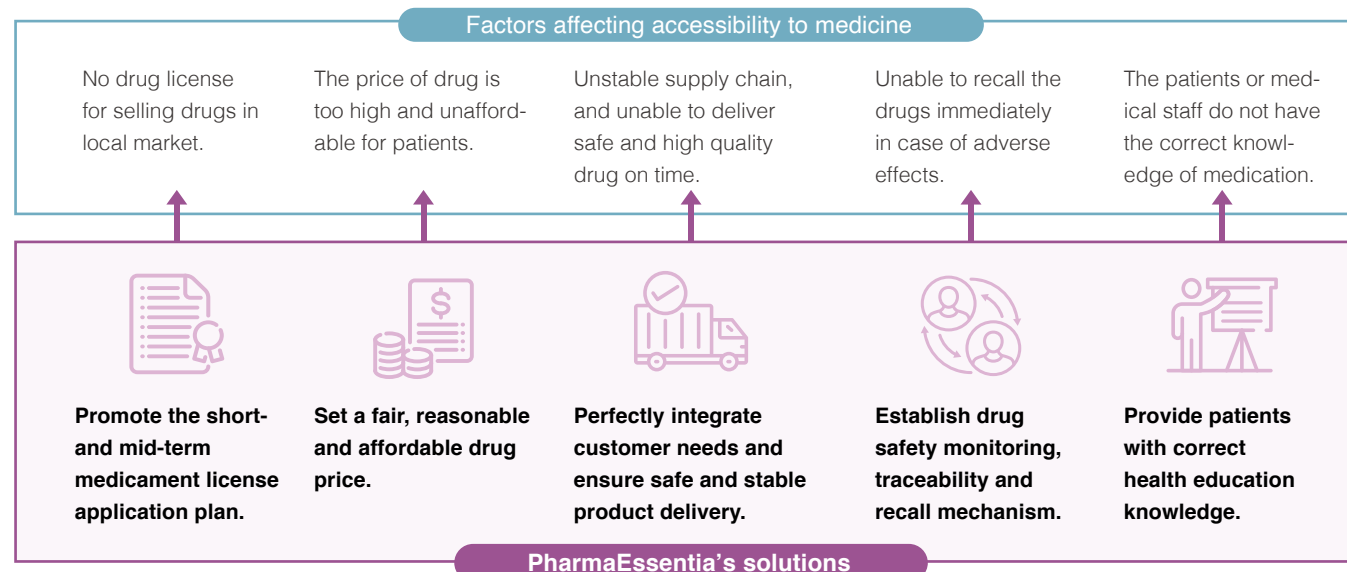
- The Company's product, Tirbanibulin Ointment (code KX 01), which was introduced under license from Athenex, Inc. in the United States, was approved by the FDA in late 2020 under the trade name Klisyri[®] for the treatment of topical skin, treatment of the face or scalp. The Company has also entered into a license agreement with Athenex to expand the territory from Taiwan, Singapore, China and Malaysia to Japan and Korea, and to expand the indications to include skin cancer and all dermatological indications, like actinic keratosis (AK). We believe that Tirbanibulin Ointment will revolutionize and change the treatment paradigm for actinic keratosis and provide an excellent treatment option for patients in Asia, especially in Taiwan, Japan and Korea.
- The oral paclitaxel Oraxol[®], a cancer drug developed in collaboration with Athenex, Inc. in the U.S., has obtained exclusive licenses in Taiwan, Singapore and Vietnam and is expected to be ready for marketing licenses in the U.S., Taiwan, Singapore and Vietnam in 2021.

6-4

A stable, safe and high-quality drug supply chain

SASB HC-BP-240a.1

At PharmaEssentia, “supply chain management” involves more than just upstream suppliers, we go further and think from the patient’s perspective to ensure timely, safe and high quality access to medicines. We have taken this goal and extrapolated it back to the management actions we need to set in place for the access to medicine, examining and considering the factors in our value chain that may affect patient medications and developing our solutions accordingly.



Short- and mid-term drug license application plans

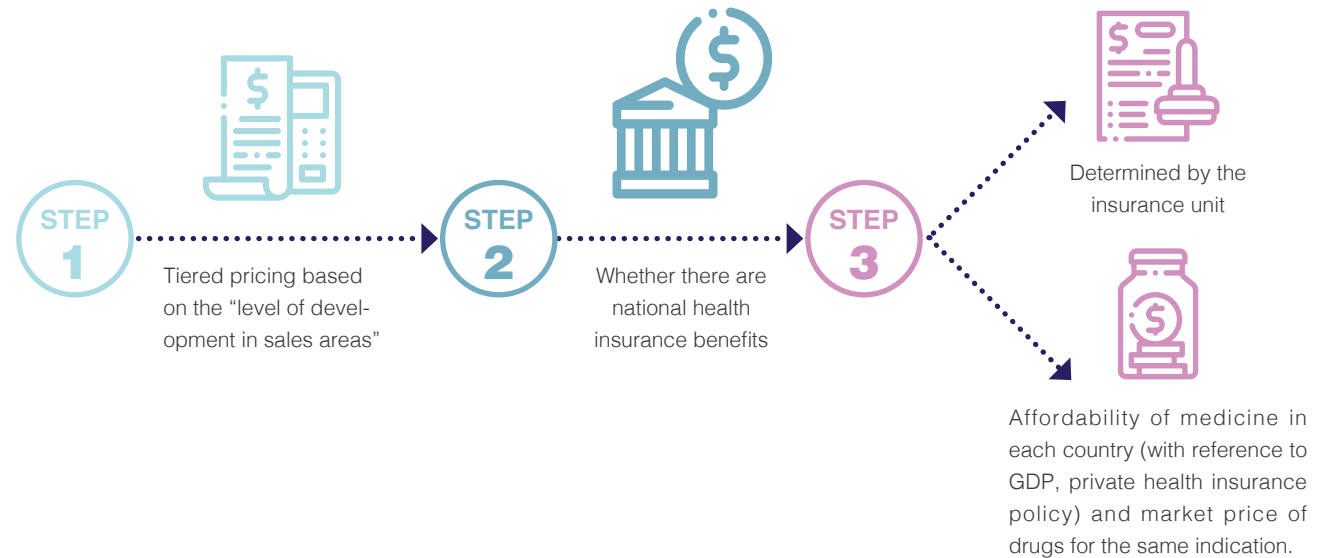
We have successfully developed the product Ropeginterferon alfa-2b (P1101) for the treatment of rare blood disorders and have successfully obtained drug certificates for the treatment of PV in the European Union, Taiwan, Switzerland, Liechtenstein, and Israel. In the future, we will continue to submit applications to the competent authorities of various countries for marketing licenses for Ropeginterferon alfa-2b (P1101) for the treatment of rare blood disorders such as PV and ET. We hope to bring the drug into all corners of the world as soon as possible for the treatment of patients with rare diseases, bringing new hope to their lives.



Fair, reasonable, and affordable drug pricing

SASB HC-BP-240b.3

The patients' rights are the priority pricing criteria of PharmaEssentia's medicine. As only through fair, reasonable and affordable prices can all patients in need be taken care of. However, in addition to considering the financial ability of patients, we also take into consideration the overall factors covering the R&D costs invested, the number of patients during the patent term, competitive products and expected profits, third-party insurance companies, or the competent authorities of various countries when setting drug prices. At present, the Company's pricing strategy is to formulate reasonable and fair prices based on the affordability of medical expenses in various countries with reference to the ["WHO Guideline on Country Pharmaceutical Pricing Policies"](#) issued by the World Health Organization (WHO), and make necessary adjustments according to economic development of the target country and pharmaceutical costs. For example, the first criterion for drawing up our "Tiered Pricing" model is the level of development in each sales area. The second criterion is whether the drug is covered by national insurance in the region where it is sold, such as Taiwan, Korea, Japan, the United Kingdom, Australia, etc. Their drug prices will primarily be approved by the national insurance unit. As for other areas, we take into consideration the gross domestic product (GDP) of each country and the affordability of medical expenses for private health insurance units. The third criterion is the market price of drugs for similar diseases.



The Company's marketing and market monopoly rights in Europe, the Middle East, and the Independent National Association market are authorized to AOP Orphan. AOP Orphan, the Company's European strategic partner, uses "value-based pricing (VBP)" method to set the price of Besremi® (Ropeginterferon alfa-2b (P1101)). For example, the prices of Besremi® in Germany and Austria are within the tiered pricing of developed countries, the prices are equivalent to the prices of other drugs for the same disease, and the drug prices are within a reasonable range for the patients. Besremi® is a medicine that requires a doctor's prescription in Taiwan. Taiwan's prescription drugs are mostly paid for by the National Health Insurance, and the government determines drug prices in accordance with the national budget and regulations on health insurance drugs. Therefore, the pricing of Besremi® in Taiwan will be based on the principles of drug price setting for National Health Insurance, taking into account clinical opinions, proof of efficacy, current treatment costs, recent national benefit budget guidelines, etc., and proposing benefit specifications, drug price planning, 5-year budget and budget impact analysis (BIA) in order to successfully obtain national insurance coverage.

Ensure safe, stable and timely delivery of medicines to meet patients' needs

Many patients with rare diseases rely highly on pharmaceutical companies for continuous supply of safe and reliable medicines to sustain their lives and quality of life. Therefore, a stable and continuous supply of high-quality medicines is an indispensable part of ensuring the patients' accessibility of medicines. We integrate clinical and market needs through inter-departmental production and sales coordination meetings on an as-needed basis, and confirm the production schedule with the supply side and the production side in order to ensure an impeccable value chain. We establish safety stock mechanism in case of raw material procurement delays, unexpected orders or other urgent use. The production, manufacturing and transportation processes are in accordance with GMP and GDP international standards. The Asian market is filled and packaged by a Taiwan needle filling factory, while the European and US markets are

entrusted to qualified and professional international OEMs and logistics providers to ensure product stability and timely and effective supply. We monitor the safety of drugs in various markets and follow GVP regulations to ensure the safety of patients using drugs. In the event of a drug recall due to manufacturing defects, product deterioration, counterfeit products or any other serious product quality problems, the product will be recalled and the related inventory disposed of within the time limit specified by the competent authority. We ensure safe, stable, and timely delivery of drugs to patients through quality management before, during, and after production, and then after the drugs are released to the market to meet patients' needs. Please refer to [Chapter 3](#) for a complete description of our quality and safety assurance at each stage of the product life cycle.





Patient education and care

After obtaining approval from the Taiwan TFDA for Ropeginterferon alfa-2b (P1101) for the treatment of PV in 2020, we have also actively started the Patient Assistant Program. Patients with MPN disease can learn about MPN disease and medical news through our [health education platform “MPNiCare.”](#) Through this support platform, we hope to integrate medical resources for patients and their families and friends to face the disease together. In addition, we will also plan to provide self-funded projects and produce a variety of health education materials and tools. For offline physical patient health education and assistance activities, we organize patient activities and support programs through external third-party entities. In 2020, a total of 96 participants participated in rare hemophilia education programs at hospitals in Taiwan. In order to ensure that PharmaEssentia’s employees interact with healthcare professionals in a reasonable manner and in accordance with relevant drug and medical regulations, we have received internal training and legal awareness, and strictly adheres to the International Research-Based Pharmaceutical Manufacturers Association (IRPMA) ethical guidelines for pharmaceutical marketing.



MPN INTERFERON INITIATIVE

In addition to Taiwan, we are also actively interacting with patients through various organizations around the world to understand their needs and support related research development. For example, in the United States, PharmaEssentia provides long-term sponsorship for the “MPN Advocacy and Education International”, and “MPN Research Foundation”. MPN Advocacy and Education International provide the knowledge needed by patients or medical staff related to myeloproliferative neoplasms (MPN) through websites, educational seminars and web conferences. The MPN Research Foundation promotes related research on myeloproliferative neoplasms (MPN) therapy, and has established “[The MPNRF Interferon \(IFN\) Initiative](#)” since 2017. Through this project, MPNRF brings together international hematology oncologists to conduct related research on interferon and myeloproliferative neoplasms (MPN) diseases, hoping to bring new discoveries to the treatment for MPN and apply them to the treatment for other cancers.

6-5

Leading the industry development

SASB HC-BP-240a.1

From Taiwan, to the world

“Remember the original intention” is the belief that PharmaEssentia upholds since its establishment 17 years ago. As a new drug company, its “original intention” is to develop new drugs to treat patients and to become a benchmark of new biopharmaceutical company among the Chinese community worldwide. With our core capabilities, we actively participate in experience sharing activities with Taiwan’s local companies in the same industry, government units, and value chain partners. With the Company’s own experience in the establishment of a complete and excellent quality system, we assisted our contract research organization partner, Agricultural Technology Research Institute, to obtain the EU certification for GMP laboratory. It has successfully obtained the certification and become the first biosafety testing laboratory in Taiwan. In the future, we hope, with our profound influence in the industry, we aim to enhance our and Taiwan’s overall contribution to the use of drugs in the global disease market.

Sponsor to hold MPN Asia

In view of the lack of first-line drugs for myeloproliferative neoplasms (MPN), and an absence of annual conferences regarding myeloproliferative neoplasms in Taiwan (only in America and Europe), PharmaEssentia began sponsoring MPN Asian in 2016. The conference brings together experts and clinicians from many countries for in-depth interaction and academic exchange on the research and treatment of blood diseases. The 5th MPN Asia Symposium, scheduled to be held in Tai-

pei, Taiwan in 2020, was cancelled due to the impact of the COVID-19 pandemic. Therefore, for the first time in 2021, we are sponsoring a global online symposium to allow physicians and scholars around the world who are concerned about MPN disease to continue to exchange experiences with the latest research and treatment modalities during pandemic. For more information about the MPN Asia Forum 2021, please visit the MPN Asia 2021 website.

Results of MPN Asia sponsorship in the past years

Year	Result description
2016	The first MPN Asia, organized by the Society of Hematology of the Republic of China, was held for the first time in Taipei, Taiwan. It facilitates the gathering of world-class experts and scholars, gains the attention of international hematology oncologists and scholars, and becomes one of the landmark international seminars
2017	The second MPN Asia was in Tokyo, Japan, and was broadcast live simultaneously in Taipei, Taiwan. Invited important medical doctors from Europe, the United States, Japan, and Taiwan to publish the latest MPN drug development and disease treatment methods. Ko-Chung Lin, CEO of PharmaEssentia, expressed that through this international medical conference, he hopes to improve Taiwan’s research status in the field of blood diseases, and promote exchanges with doctors of blood diseases in Europe, the United States, and Japan, and promote everyone’s attention to the treatment of blood diseases.
2018	The 3rd MPN Asia was held in Hangzhou, China. As usual, key opinion leaders (KOLs) from Europe, the United States, Japan, China and Taiwan were invited to present the latest drug development and disease treatment approaches, and the agenda was divided into basic science and focus topics of MPN. Jointly witnessed the excellent clinical trial data of next generation interferon in the treatment of blood diseases.
2019	The 4th MPN Asia was held in Seoul, Korea to exchange treatment and clinical data from around the world for the treatment of MPN. In addition, through the annual conferences, we can help increase the visibility of Taiwan’s new drug R&D capability, and win honor for Taiwan.

Appendices

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Appendix 2	GRI Standards Comparison Table	162
Appendix 3	United Nation Global Compact Comparison Table	171
Appendix 4	SASB Index Table	172
Appendix 5	Statement of Independent Assurance Opinion	176

Appendix 1

About our Sustainability Report

Reporting period

GRI 102-50~52

This report published on September, 2021 is the second CSR report issued by PharmaEssentia, and its reporting period is from January 1 to December 31, 2020. The content encompasses the Company's specific actions taken and performances in the aspects of Environment (E), Society (S) and Corporate Governance (G). In order to fully present the performance of the Company's medium and long-term projects in our first CS report, and for the comparability and time-liness, part of the content covers the information up to March 31, 2021. Future CS reports will be prepared on a yearly basis.

Scope of report

GRI 102-45

GRI 102-46

- The scope of data disclosed in this report is mainly based on the Taiwan headquarter of PharmaEssentia and its Taiwan subsidiary, Panco Healthcare, and the incomplete details are as follows, which are noted in the corresponding content of the report:
 - For the human resources-oriented data in Chapter 4, there are some data not yet collected until 2020 by Panco Healthcare, a subsidiary in Taiwan, which are noted in the corresponding content and will continue to be collected and fully disclosed in the future. In addition, only the manpower structure table and performance appraisal cover the U.S. subsidiaries, while the rest do not cover the U.S. subsidiaries.
 - For the environmental data in Chapter 5, there are still some data that cannot be collected until 2020 by Panco Healthcare. There are remarks in the corresponding content and will continue to be collected and disclosed in the future.
- The financial information is based on publicly disclosed Group consolidated financial statements.
- In the future, the CS Report of PharmaEssentia will gradually expand the disclosure boundary to cover the overall information of the Group.

Reporting principle

GRI 102-54

- This report is prepared in accordance with the "GRI Standards: 2016" issued by the Global Reporting Initiative (GRI), and is disclosed with reference to the Core Option. The themes of "GRI 303: Water and Effluents" and "GRI 403: Occupational Health and Safety" adopt the updated GRI guidelines in 2018, and the theme of "GRI 306: Waste" adopts the updated GRI guidelines in 2020.
- This report is also prepared with reference to the following guidelines:
 - AA1000 Account Ability Principles 2018
 - UN Global Compact (Please refer to [Appendix 3](#))
 - UN Sustainable Development Goals (SDGs)
 - ISO 26000 Social Responsibility Guidance
 - Sustainability Accounting Standard Board (SASB)
 - Access to Medicine Index 2020

Report management process

GRI 102-32

Execution Center for Corporate Sustainability (ECCS) is responsible for planning and promoting cross-departmental and unit-related corporate sustainable development policies, goals, strategies and sustainable development implementation plans and other related affairs. Five inter-departmental functional taskforces, including the “Corporate Governance, Product Quality and Patient Safety, Employee Care, Environmental Friendliness, and Access to the Medicine” carry out relevant plans. A representative from the ECCS will report the progress of the project to the Board of Directors on a quarterly basis. The information and project contents disclosed in this report are provided by the Company’s various responsible departments, collected and compiled by the ECCS, and published after the information and the project contents are audited by corresponding functional teams and approved by responsible supervisors.

External assurance

GRI 102-56

This report was commissioned by the British Standards Institution Taiwan (BSI Taiwan) in accordance with the AA1000 Assurance Standard (Assurance Standard, 2008) v3, at the Type I medium assurance level. Please refer to Appendix 5 of this report for details of the warranty statement.

Contact

GRI 102-53

We would like to know your suggestions and thoughts. If you have any needs, please contact us.

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Appendix 2

GRI Standards Comparison Table

GRI 102-55

GRI 102: General Disclosures 2016				
Disclosure indicator	Description	Reference section	Page number	Notes
Organization profile				
102-1	Name of the organization	1.1 A fully integrated innovative biopharmaceutical company	20	
102-2	Activities, brands, product, and services			
102-3	Location of headquarters			
102-4	Location of operations			
102-5	Ownership and legal form			
102-6	Markets served			
102-7	Scale of the organization			
102-8	Information on employees and other workers	4.1 A happy workplace	107	There are no major changes in the number of employees in 2020.
102-9	Supply chain	3.2 Accountable Supplier Management	83	
102-10	Significant changes to the organization and its supply chain			There are no major changes in the supply chain in 2020.
102-11	Precautionary Principle or approach	2.4 Risk and crisis management	60	
102-12	External initiatives			The Company is not a signatory of any external initiatives.
102-13	Membership of associations			The Company is a member of 14 associations, societies and organizations related to the biotechnology and pharmaceutical industry, including the Taiwan Pharmaceutical Manufacturer's Association, the Taiwan Research-based Biopharmaceutical Manufacturers Association, and the Hematology Society of Taiwan.
Strategy				
102-14	tatement from senior decision-maker	Preamble 3. Messages from the management team 1.2 Two major globalization policies	6 22	

GRI 102: General Disclosures 2016				
Disclosure indicator	Description	Reference section	Page number	Notes
Materiality: Risk Management				
Strategy				
102-15	Key impacts, risks, and opportunities	2.4 Risk and crisis management	60	
Management Approach				
103-2	The management approach and its components	2.4 Risk and crisis management	58	
103-3	Evaluation of the management approach			
Ethics and integrity				
102-16	Values, principles, standards, and norms of behavior	Preamble 1. Better science, Better lives - Purpose of PharmaEssentia Corporation	3	
102-17	Mechanisms for advice and concerns about ethics	2.3 Compliance and business ethics	56	No ethical or illegal acts and no reports of corporate integrity in 2020.
Materiality: Corporate Governance				
Governance				
102-18	Governance structure	2.2 Corporate governance and management	47	
Management Approach				
103-2	The management approach and its components	2.2 Corporate governance and management	44	
103-3	Evaluation of the management approach			
Governance				
102-19	Delegating authority	2.1 ESG governance	39	
102-20	Executive-level responsibility for economic, environmental, and social topics			
102-23	Chair of the highest governance body			The Chairman of the highest governance unit of the Company is not a member of the management team.
102-31	Review of economic, environmental, and social topics	2.1 ESG governance	39	
102-32	Highest governance body's role in sustainability reporting	2.1 ESG governance Appendix 1 About our Sustainability Report	39 160	
102-33	Communicating critical concerns	2.1 ESG governance	39	

GRI 102: General Disclosures 2016

Disclosure indicator	Description	Reference section	Page number	Notes	
Stakeholder engagement					
102-40	List of stakeholder groups	Preamble 5. Identification of Stakeholders	15		
102-41	Collective bargaining agreements			The Company has not established a labor union, and thus there is no collective agreement. However, the Company holds labor relation meetings on a regular basis as one of the communication channels for employees.	
102-42	Identifying and selecting stakeholders	Preamble 5. Identification of Stakeholders	15		
102-43	Approach to stakeholder engagement	Preamble 5. Identification of Stakeholders			
102-44	Key topics and concerns raised	Preamble 5. Identification of Stakeholders			
Reporting practice					
102-45	Entities included in the consolidated financial statements	Appendix 1 About our Sustainability Report	160		
102-46	Defining report content and topic Boundaries	Preamble 4. Our Identification process of sustainability topics	8		
		Appendix 1. About our Sustainability Report	160		
102-47	List of material topics	Preamble 4. Our Identification process of sustainability topics	11		
102-48	Restatements of information			In 2020, the Company acquired Panco Healthcare as a 100% owned subsidiary, which is included in the reporting boundary of this report. Please refer to Appendix 1 for more details.	
102-49	Changes in reporting	Preamble 4. Our Identification process of sustainability topics	12		
102-50	Reporting period	Appendix 1. About our Sustainability Report			
102-51	Date of most recent report				
102-52	Reporting cycle				
102-53	Contact point for questions regarding the report				
102-54	Claims of reporting in accordance with the GRI Standards				

GRI 102: General Disclosures 2016

Disclosure indicator	Description	Reference section	Page number	Notes
Reporting practice				
102-55	GRI content index	Appendix 2. GRI Standards Comparison Table	162	
102-56	External assurance	Appendix 1. About our Sustainability Report Appendix 5. Statement of Independent Assurance Opinion	160 176	

GRI 103: Management Approach 2016

Disclosure indicator	Description	Reference section	Page number	Notes
Management Approach				
103-1	Explanation of the material topic and its Boundary	Preamble 4. Our Identification process of sustainability topics	12	

GRI 200: Topic-Specific Standards Economic Topics 2016

Disclosure indicator	Description	Reference section	Page number	Notes
Economic Performance				
201-1	Direct economic value generated and distributed	2.2 Corporate governance and management	50	
201-3	Defined benefit plan obligations and other retirement plans	4.2 Competitive compensation and benefits	111	The Company guarantees the retirement benefits of all employees pursuant to the provisions of the pension system of the Labor Standards Act of Taiwan.
201-4	Financial assistance received from government			The total amount of financial assistance from the government in 2020 is approximately NT\$23.76 million.
Market Presence				
202-2	Proportion of senior management hired from the local community	4.1 A happy workplace	107	

GRI 200: Topic-Specific Standards Economic Topics 2016

Disclosure indicator	Description	Reference section	Page number	Notes
Materiality: Access to Medicine				
Indirect Economic Impacts				
203-1	Infrastructure investments and services supported	6.1 Access to medicine strategies	145	
Management Approach				
103-2	The management approach and its components	6.1 Access to medicine strategies	145	
103-3	Evaluation of the management approach			
Procurement Practices				
204-1	Proportion of spending on local suppliers	3.2 Accountable Supplier Management	82	
Anti-corruption				
205-3	Confirmed incidents of corruption and actions taken			There were no incidents of corruption in 2020 .
Anti-competitive Behavior				
206-1	Legal actions for anticompetitive behavior, anti-trust, and monopoly practices			In 2020, there were no legal actions for anti-competitive behavior.

GRI 300: Topic-Specific Standards Environmental Topics 2016

Disclosure indicator	Description	Reference section	Page number	Notes
Energy				
302-3	Energy intensity	5.1 Climate Change Mitigation Strategy	128	
Water and Effluents (2018)				
303-3	Water withdrawal	5.4 Water resources management	129	
303-4	Water discharge			
303-5	Water consumption			
Emissions				
305-6	Emissions of ozone-depleting substances (ODS)	5.1 Climate Change Mitigation Strategy	129	
305-7	Nitrogen oxides (NOx), sulfur oxides (SOx), and other significant air emissions			

GRI 300: Topic-Specific Standards Environmental Topics 2016

Disclosure indicator	Description	Reference section	Page number	Notes
Materiality: Waste management				
Waste (2020)				
306-1	Waste generation and significant waste-related impacts			The Company is still evaluating the significant impact of the inputs, activities and waste generated, and will gradually complete the data collection and disclose the information in the future.
306-2	Management of significant waste-related impacts	5.2 Waste management	133	
306-3	Waste generated			
306-4	Waste diverted from disposal		134	
306-5	Waste directed to disposal			
Management Approach				
103-2	The management approach and its components	5.2 Waste management	130	
103-3	Evaluation of the management approach			

GRI 400: Topic-Specific Standards Social Topics 2016

Disclosure indicator	Description	Reference section	Page number	Notes
Employment				
401-1	New employee hires and employee turnover	4.1 A happy workplace	109	
401-2	Benefits provided to fulltime employees that are not provided to temporary or part-time employees	4.2 Competitive compensation and benefits	111	
401-3	Parental leave		112	
Labor / Management Relations				
402-1	Minimum notice periods regarding operational changes			All matters are handled in accordance with the relevant provisions of the Labor Standards Act.
Materiality: Occupational Health and Safety				
Occupational Health and Safety (2018)				
403-3	Occupational health services	4.5 Occupational health and safety	119	
403-5	Worker training on occupational health and safety		122	

GRI 400: Topic-Specific Standards Social Topics 2016

Disclosure indicator	Description	Reference section	Page number	Notes
403-7	Prevention and mitigation of occupational health and safety impacts directly linked by business relationships	4.5 Occupational health and safety	122	
403-9	Work-related injuries			
403-10	Work-related ill health			
Management Approach				
103-2	The management approach and its components	4.5 Occupational health and safety	118	
103-3	Evaluation of the management approach			
Materiality: Talent Cultivation and Career Development				
Training and Education				
404-1	Average hours of training per year per employee	4.4 Talent training and career development	116	
404-3	Percentage of employees		117	
Management Approach				
103-2	The management approach and its components	4.4 Talent training and career development	114	
103-3	Evaluation of the management approach			
Diversity and Equal Opportunity				
405-1	Diversity of governance bodies and employees	2.2 Corporate governance and management 4.1 A happy workplace	47	
405-2	Ratio of basic salary and remuneration of women	4.2 Competitive compensation and benefits	107	
Non-discrimination				
406-1	Incidents of discrimination and corrective actions taken	4.2 Competitive compensation and benefits	110	There were no incidents of discrimination in 2020.
Forced or Compulsory Labor				
409-1	Operations and suppliers at significant risk for incidents of forced or compulsory labor			There were no incidents of forced-labor in 2020.
Rights of Indigenous Peoples				
411-1	Incidents of violations involving rights of indigenous peoples			There were no incidents of violation of the rights of indigenous peoples in 2020.

GRI 400: Topic-Specific Standards Social Topics 2016				
Disclosure indicator	Description	Reference section	Page number	Notes
Human Rights Assessment				
412-1	Operations that have been subject to human rights reviews or impact assessments			The Company is not involved in operations that have been subject to human rights reviews or impact assessments. However, it has formulated the Human Right Policy for preliminary management.
Customer Health and Safety				
416-2	Incidents of noncompliance concerning the health and impacts of products and services			No incidents violating regulatory compliance occurred in 2020.
Materiality: Data Privacy and Cybersecurity				
Customer Privacy				
418-1	Substantiated complaints concerning breaches of customer privacy and losses of customer data	2.5 Rigorous data privacy and cybersecurity	67	No incidents violating regulatory compliance occurred in 2020.
Management Approach				
103-2	The management approach and its components	2.5 Rigorous data privacy and cybersecurity	67	
103-3	Evaluation of the management approach			

PharmaEssentia Corporation and Industry-exclusive topics				
Materiality: Compliance and business ethics				
Management Approach				
103-2	The management approach and its components	2.3 Compliance and business ethics	51	
103-3	Evaluation of the management approach			
Materiality: Intellectual property rights				
Management Approach				
103-2	The management approach and its components	2.6 Comprehensive management of intellectual property rights	70	
103-3	Evaluation of the management approach			

GRI 400: Topic-Specific Standards Social Topics 2016

Disclosure indicator	Description	Reference section	Page number	Notes
Materiality: Innovative drugs research and discovery				
Management Approach				
103-2	The management approach and its components	1.3 R&D of innovative biopharmaceuticals	24	
103-3	Evaluation of the management approach			
Materiality: Stable and secure supply chain				
Management Approach				
103-2	The management approach and its components	3.1 Constructing a comprehensive supply chain system	78	
103-3	Evaluation of the management approach			
Materiality: Product Quality and Safety Management				
Management Approach				
103-2	The management approach and its components	3.3 Ensuring the quality and safety of drugs	87	
103-3	Evaluation of the management approach			
Materiality: Patient Safety				
Management Approach				
103-2	The management approach and its components	3.6 Effective pharmacovigilance and recall mechanism	98	
103-3	Evaluation of the management approach			
Materiality: Toxic Chemicals Management				
Management Approach				
103-2	The management approach and its components	5.3 Toxic chemical substances management	135	
103-3	Evaluation of the management approach			






Appendix 3







United Nation Global Compact Comparison Table







Category	Ten Principles	Description	Referenced Chapter	
Human Rights	(1) Businesses should support and respect the protection of internationally proclaimed human rights.	The Company abides by the UN Global Compact, Universal Declaration of Human Rights and "International Labour Convention" and other international human rights conventions.	4.3 Human rights protection	
	(2) Make sure that they are not complicit in human rights abuses.			
Labor	(3) Businesses should uphold the freedom of association and the effective recognition of the right to collective bargaining.	The Company holds regular labor relation meetings.		
	(4) The elimination of all forms of forced and compulsory labor	There were no incidents of forced labor, child labor, or discrimination in any form.		
	(5) The effective abolition of child labor.			
	(6) The elimination of discrimination in respect of employment and occupation.			
Environment	(7) Businesses should support a precautionary approach to environmental challenges.	For the aspect, Environment (E), the Company step-by-step introduces an ISO management system and the Task Force on Climate-related Financial Disclosures (TCFD) as the disclosure framework.		5.1 Climate Change Mitigation Strategy
	(8) Undertake initiatives to promote greater environmental responsibility.	Complying with laws and regulations, the Company manages well the waste control, and requiring suppliers to implement jointly the commitment to environmental friendliness and prevent leakage of chemical substances.		5.2 Waste management
	(9) Encourage the development and diffusion of environmentally friendly technologies.			5.3 Toxic chemical substances management
Anti-Corruption	(10) Businesses should work against corruption in all its forms, including extortion and bribery	The Company will formulate its Anticorruption Code with reference to the United Nations Convention against Corruption (UNCAC).		2.3 Compliance and business ethics










Appendix 4

SASB Index Table

Code	Accounting Metric	Disclosure	Referenced Chapter	Corresponding SDGs	Page number
Topic: Safety of Clinical Trial Participants					
HC-BP-210a.1	Discussion, by world region, of management process for ensuring quality and patient safety during clinical trials	The risk assessment for clinical trials is performed by a CRO, and the internal standard operating procedure "Vendor Selection and Management" is the main requirement for performing quality assurance and quality management activities in clinical trials. There are no cases of clinical trials discontinued with CROs due to GCP violations. At each stage of clinical development, we have an audit and inspection mechanism and comply with the "Declaration of Helsinki" and the "International Council for the Regulation of Pharmaceuticals Good Clinical Practice (ICH-GCP)." Written informed consent shall be obtained from the subjects before the clinical trials are officially launched, and strictly screening suitable subjects according to the inclusion and exclusion criteria of the investigational new drug (IND) application.	1.3 R&D of innovative biopharmaceuticals		29
HC-BP-210a.2	Number of FDA Sponsor Inspections related to clinical trial management and pharmacovigilance that resulted in: (1) Voluntary Action Indicated (VAI) and (2) Official Action Indicated (OAI)	No such information is available at this time.			
HC-BP-210a.3	Total amount of monetary losses as a result of legal proceedings associated with clinical trials in developing countries	No such information is available at this time.			
Topic: Access to Medicines					
HC-BP-240a.1	Description of actions and initiatives to promote access to health care products for priority diseases and in priority countries as defined by the Access to Medicine Index	One of the Company's 4 focused disease areas is Hematologic diseases. As of the issuance of this report, the drug BESREMi® for the treatment of PV has been sold in 18 countries in Europe. We are also sponsoring the MPN Asia for 6 consecutive years since 2016 and the American Society of Hematology (ASH) in 2020, so that physicians and scholars around the world who are concerned about MPN disease can continue to have access to the latest research and treatment modalities. The subsections of Chapter 6 of this report describe in detail of our Access to Medicine strategy, implementation plan and annual results, and future goals following the Access to Medicine Index, 2020 framework.	1.5 Global commercialization blueprint	 	32 141~158

Code	Accounting Metric	Disclosure	Referenced Chapter	Corresponding SDGs	Page number
HC-BP-240a.2	List of products on the WHO List of Prequalified Medicinal Products as part of its Prequalification of Medicines Programme (PQP)	No such drug is available at this time.			
Topic: Affordability & Pricing					
HC-BP-240b.1	Number of settlements of Abbreviated New Drug Application (ANDA) litigation that involved payments and/or provisions to delay bringing an authorized generic product to market for a defined time period	No such information is available at this time.			
HC-BP-240b.2	Percentage change in: (1) average list price and (2) average net price across U.S. product portfolio compared to previous year	No drugs have been sold in the U.S.			
HC-BP-240b.3	Percentage change in: (1) list price and (2) net price of product with largest increase compared to previous year	At present, the Company's pricing strategy is to formulate reasonable and fair prices based on the affordability of medical expenses in various countries with reference to the "WHO Guideline on Country Pharmaceutical Pricing Policies" issued by the World Health Organization (WHO). In the future, we will continue to track the price of drugs around the world to ensure patient affordability.	6.4 A stable, safe and high-quality drug supply chain		155
Topic: Drug Safety					
HC-BP-250a.1	List of products listed in the Food and Drug Administration's (FDA) Med-Watch Safety Alerts for Human Medical Products database	The Company has completed the establishment of a pharmacovigilance mechanism at the head-quarter, and the subsidiaries and other drug supplying countries or regions will complete the establishment in accordance with local regulations and drug marketing schedules. We will continue to monitor the safety and risk management of new drugs after they are launched. No drugs have been sold in the U.S., and there have been no adverse drug reaction reports or recalls of drugs sold worldwide.	3.6 Effective pharmacovigilance and recall mechanism	 	98
HC-BP-250a.2	Number of fatalities associated with products as reported in the FDA Adverse Event Reporting System				
HC-BP-250a.3	Number of recalls issued; total units recalled				
HC-BP-250a.4	Total amount of product accepted for takeback, reuse, or disposal				
HC-BP-250a.5	Number of FDA enforcement actions taken in response to violations of current Good Manufacturing Practices (cGMP), by type				

Code	Accounting Metric	Disclosure	Referenced Chapter	Corresponding SDGs	Page number
Topic: Counterfeit Drugs					
HC-BP-260a.1	Description of methods and technologies used to maintain traceability of products throughout the supply chain and prevent counterfeiting	We have established records of serial number, batch number and factory activities for each batch of pharmaceutical products to ensure batch flow and traceability, and managed and tracked them with standard operating procedures such as the “Product Code and Batch Number Coding Procedures.” We have also formulated “Product Secondary Packaging and Serialization Batch Record” to regulate the operation process of commercial packaging and serialization of products by overseas outsourced processing plants. BESREMi [®] , which is expected to be sold in the US market, has also completed the introduction of drug serialization in 2020.	3.1 Constructing a comprehensive supply chain system 3.6 Effective pharmacovigilance and recall mechanism		76 103
HC-BP-260a.2	Discussion of process for alerting customers and business partners of potential or known risks associated with counterfeit products	When a drug is reported to have a known or probable manufacturing defect, deterioration, counterfeit or any other serious quality problem, our QA department will initiate an investigation and initiate product recall procedures and recovery actions. Furthermore, according to the hazard level of drugs, we remove the drugs from the user-end within a certain period of time, properly dispose of the recovered product, and notify the local competent authority.	3.6 Effective pharmacovigilance and recall mechanism		103
HC-BP-260a.3	Number of actions that led to raids, seizure, arrests, and/or filing of criminal charges related to counterfeit products	No such information is available at this time.			
Topic: Ethical Marketing					
HC-BP-270a.1	Total amount of monetary losses as a result of legal proceedings associated with false marketing claims	No such information is available at this time.			57
HC-BP-270a.2	Description of code of ethics governing promotion of off-label use of products	In terms of marketing and labeling, we strictly follow the ethical standards of the WHO and other countries in the pharmaceutical industry. In order to ensure that our pharmaceutical employees interact with health-care professionals in a reasonable manner and in accordance with relevant pharmaceutical and medical regulations, we have received internal training and legal education on the ethical standards of pharmaceutical marketing. For more details, please refer to 2.3 Compliance and Business ethics.	2.3 Compliance and business ethics	 	

Code	Accounting Metric	Disclosure	Referenced Chapter	Corresponding SDGs	Page number
Topic: Employee Recruitment, Developing & Retention					
HC-BP-330a.1	Discussion of talent recruitment and retention efforts for scientists and research and development personnel	The Company creates a stable working environment for retaining talents through compensation and benefits, friendly environment, humane management, smooth internal rotation and training and development. We are recruiting biomedical and R&D talents in various professional fields, and actively recruiting clinical and global management professionals. We have recruited more than 30 new R&D and medical research professionals worldwide in 2020, accounting for 10% of the total workforce.	4.1 A happy workplace	  	109
HC-BP-330a.2	(1) Voluntary and (2) involuntary turnover rate for: (a) executives/senior managers, (b) midlevel managers, (c) professionals, and (d) all others	The retention rate for executive positions in 2020 was 93.94%, and the growth rate of all PharmaEssentia's employees has continued to grow steadily over the past three years. Please refer to 4.1 A Happy Workplace for details and calculations of our new entry and retention rates.	4.1 A happy workplace		109
Topic: Supply Chain Management					
HC-BP-430a.1	Percentage of (1) entity's facilities and (2) Tier I suppliers' facilities participating in the Rx-360 International Pharmaceutical Supply Chain Consortium audit program or equivalent third-party audit programs for integrity of supply chain and ingredients	Although we do not currently conduct external audits of our upstream supply chain, we have stringent internal procedures to monitor the selection, evaluation and approval of suppliers of raw materials, materials and instruments/equipment. We also conduct supplier/contractor evaluations on a regular basis each year, using a combination of internal evaluation reviews and on-site audits. For 2 consecutive years, 100% of internal assessments and field audits were completed.	3.2 Accountable Supplier Management	  	85
Topic: Business Ethics					
HC-BP-510a.1	Total amount of monetary losses as a result of legal proceedings associated with corruption and bribery	No such information is available at this time.			
HC-BP-510a.2	Description of code of ethics governing interactions with health care professionals				
Activity Metrics					
HC-BP-000.A	Number of patients treated	As of Q1 2021, BESREMI [®] is sold in 18 countries in Europe and used by nearly a thousand patients.	1.5 Global commercialization blueprint		32
HC-BP-000.B	Number of drugs (1) in portfolio and (2) in research and development (Phases 1-3)	The Company has initiated international clinical trials and has accumulated more than 19 clinical trials worldwide, benefiting up to 1,500 patients.	1.3 R&D of innovative biopharmaceuticals	 	28
			6.2 Innovative medicine - solving unmet medical needs		150

Appendix 5

Statement of Independent Assurance Opinion


GRI 102-56

Disclaimer

The information provided herein is for reference only and is not to be relied upon as making a complete description of the Company's operations. Shall the content involve any predictions, the Company does not imply, declare nor guarantee the correctness or reliability of the information provided. Users shall be solely responsible for their judgment and their undertaking of risks.

Forward-Looking Statement

Some of the statements included in this press release, particularly those relating to the results of clinical trials, the clinical benefits to be derived from Roppeginterferon alfa-2b-njft, regulatory submissions and the timing of any such review, approvals, the commercial opportunity, and competitive positioning, and any business prospects for Roppeginterferon alfa-2b-njft, may be forward-looking statements that involve several risks and uncertainties. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995 and similar legislation and regulations under Taiwanese law. Among the factors that could cause our actual results to differ materially are the following: acceptance of the BLA filing does not represent a final evaluation of the adequacy of the data submitted in the BLA; whether the FDA will complete its review of the BLA on a timely basis; the risk that the FDA ultimately denies approval of the BLA; whether the FDA concurs with our interpretation of our phase 3 study results, supportive data, or the conduct of the studies; whether Roppeginterferon alfa-2b-njft, if approved, will be successfully launched and marketed, and other risk factors identified from time to time in our reports filed with any global securities regulator or agency.



INDEPENDENT ASSURANCE OPINION STATEMENT

PharmaEssentia Corporation 2020 Sustainability Report

The British Standards Institution is independent to PharmaEssentia Corporation (hereafter referred to as PharmaEssentia) in this statement and has no financial interest in the operation of PharmaEssentia other than for the assessment and verification of the sustainability statements contained in this report.

This independent assurance opinion statement has been prepared for the stakeholders of PharmaEssentia only for the purposes of assuring the statements relating to its corporate social responsibility (CSR), more particularly its environmental, social and governance (ESG) performance. It is not intended for any other purpose. The British Standards Institution will not be providing this independent assurance opinion statement, social or assurance responsibility (legal or otherwise) or any other liability for or in connection with any other purpose for which it may be used, or in any person by whom the independent assurance opinion statement may be used.

This independent assurance opinion statement is prepared on the basis of review by the British Standards Institution of information presented to it by PharmaEssentia. The review does not extend beyond such information and is solely based on it. In performing such review, the British Standards Institution has assumed that all such information is complete and accurate.

Any opinion that may arise by virtue of this independent assurance opinion statement or matters relating to it should be addressed to PharmaEssentia only.

Scope

The scope of engagement agreed upon with PharmaEssentia includes the following:

- The assurance scope is consistent with the description of PharmaEssentia Corporation 2020 Sustainability Report.
- The evaluation of the nature and extent of the PharmaEssentia's adherence to AA1000 Accountability Principles (2018) in this report as contained in accordance with type 1 of AA1000 ISO sustainability assurance engagement and therefore, the information/data disclosed in the report is not verified through the verification process.

This statement was prepared in English and translated into Chinese for reference only.

Opinion Statement

We conclude that the PharmaEssentia Corporation 2020 Sustainability Report provides a fair view of the PharmaEssentia CSR programmes and performance during 2020. The CSR report subject to assurance is free from material misstatement based upon findings within the limited scope of the assurance, the information and data provided by the PharmaEssentia and the sample taken. We believe that the 2020 economic, social and environmental performance information is fairly represented. The CSR performance information disclosed in this report contains PharmaEssentia's best representation of its performance.

Our work was carried out by a team of CSR report assessors in accordance with the AA1000AS v3. We planned and performed this part of our work to obtain the necessary information and explanation we considered to provide sufficient evidence that PharmaEssentia's description of their approach to AA1000AS v3 and their self-declaration in accordance with GRI Standards. Core option was only used.

Methodology

Our work was designed to gather evidence on which to base our conclusion. We undertook the following activities:

- a review of issues raised by external parties that could be relevant to PharmaEssentia's policies to provide a check on the appropriateness of statements made in the report
- discussion with managers on approach to stakeholder engagement. However, we had no direct contact with external stakeholders.
- 30 interviews with staffs involved in sustainability management, report preparation and provision of report information were carried out.
- review of key organizational developments.
- review of the findings of internal audits.
- review of supporting evidence for claims made in the reports.
- an assessment of the organization's reporting and management processes concerning this reporting against the principles of Inclusivity, Materiality, Responsiveness and Impact as described in the AA1000AP (2018).

Conclusions

A detailed review against the Inclusivity, Materiality, Responsiveness and Impact of AA1000AP (2018) and GRI Standards is set out below.

Inclusivity

This report has reflected a fact that PharmaEssentia has sought the engagement of its stakeholders and established material sustainability topics, as the participation of stakeholders has been conducted in developing and achieving an inclusive and strategy response to sustainability. There are fair reporting and disclosure for economic, social and environmental information in this report so that appropriate planning and target setting can be supported. In our professional opinion the report covers the PharmaEssentia's material issues.

Materiality

PharmaEssentia publishes material topics that will substantively influence and impact the assessments, decisions, actions and performance of PharmaEssentia and its stakeholders. The sustainability information disclosed enables its stakeholders to make informed judgments about the PharmaEssentia's management and performance. In our professional opinion the report covers the PharmaEssentia's material issues.

Responsiveness

PharmaEssentia has implemented the practice to respond to the expectations and perceptions of its stakeholders. An Ethical Policy for PharmaEssentia is developed and continually provides the opportunity to further enhance PharmaEssentia's responsiveness to stakeholder concerns. Topics that stakeholder concern about have been responded timely. In our professional opinion the report covers the PharmaEssentia's responsiveness issues.

Impact

PharmaEssentia has identified and fairly represented impacts that were measured and disclosed in a probably balanced and effective way. PharmaEssentia has established processes to monitor, measure, evaluate and manage impacts that lead to more effective decision-making and health-based management within the organization. In our professional opinion the report covers the PharmaEssentia's impact issues.

GRI Sustainability Reporting Standards (GRI Standards)

PharmaEssentia provided out with their self-declaration of its accordance with GRI Standards. Core option (for least material facts covered) is a topic-specific GRI Standard. Consistently with all reporting requirements for at least one topic-specific disclosure. Based on our review, we confirm that social responsibility and sustainable development disclosures with reference to GRI Standards, disclosures are reported, properly reported or omitted in our professional opinion the self-declaration covers the PharmaEssentia's social responsibility and sustainability issues.

Assurance level


The material level assurance provided is in accordance with AA1000AS v3 in our review, as defined by the scope and methodology described in this statement.

Responsibility

The GRI report is the responsibility of the PharmaEssentia's chairman as declared in his responsibility letter. Our responsibility is to provide an independent assurance opinion statement to stakeholders giving our professional opinion based on the scope and methodology described.

Competency and independence

The assurance team was composed of lead auditors experienced in relevant sectors, and trained in a range of sustainability, environmental and social standards including AA1000AS, ISO 14001, ISO 45001, ISO 14064 and ISO 26001. BSI is a leading global standards and assessment body founded in 1901. The assurance is carried out in line with the ISO Fair Trading Code of Practice.

For and on behalf of BSI: 
Peter Pu, Managing Director BSI Taiwan

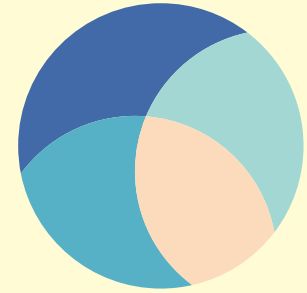
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PharmaEssentia Corporation



2020 Sustainability Report

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PharmaEssentia

