5.4 Patient Safety Management

GRI 417-1/417-2

To fulfill strict requirements for drug quality, our company adheres to the highest standards for product services and labeling, which comply with international and domestic government regulations (such as the European Medicines Agency and the US Food and Drug Administration). After a product is launched, a series of safety tracking actions are initiated. Since 2021, PharmaEssentia has established a thorough global pharmacovigilance mechanism and continues to conduct safety monitoring and risk control for new drugs after they are launched. In 2022, we did not violate any related regulations on product service labeling, and complied with pharmacovigilance and compliance requirements worldwide. We continue to optimize drug safety policies and internal standard operating procedures to help maintain the health and safety of patients.

Global Drug Safety Monitering Mechanism for Ropeginterferon alfa-2b (P1101)

AOP Orphan GmbH
European authorized partner
Health Regulatory Authority:
European Medicines Agency (EMA)

PharmaEssentia Biosciences (Beijing) Co., Ltd.
Chinese subsidiary
Health Regulatory Authority:
National Medical Products Administration (NMPA)

PharmaEssentia Asia Limited
Hong Kong subsidiary
Health Regulatory Authority: Drug Office of the Department of Health (DOH)

PharmaEssentia Korea Corporation
Korean subsidiary
Regulatory authority: Ministry of Food and Drug Safety (MFDS) in South Korea.

PharmaEssentia Japan KK
Japanese subsidiary
Health authority: Pharmaceuticals and Medical Devices Agency (PMDA)

PharmaEssentia USA Corporation
US subsidiary
Health authority:
US Food and Drug Administration (FDA)

Taiwan
PharmaEssentia
PharmaEssentia Corporation Headquarter
Commissioned agency by Taiwan Food and Drug Administration (TFDA)
National Adverse Drug Reaction Reporting System (ADR center)

Global Pharmacovigilance and Reporting Procedure

SASB HC-BP-250a.1 / a.2 / a.3 / a.4 / a.5

The company's pharmacovigilance department is under the jurisdiction of the Medical Research Department, and works in conjunction with relevant departments according to the Pharmacovigilance Policy, the Drug Safety Training Standard Operating Procedures, and the Post-Marketing Safety Data Collection Standard Operating Procedures. In addition to PharmaEssentia Headquarters, each subsidiary or region also has personnel dedicated to pharmacovigilance. Since 2022, a Global Vice President of Pharmacovigilance and an Global Executive Director of Pharmacovigilance have been appointed to be responsible for global pharmacovigilance. At the same time, an external pharmacovigilance CRO company has been commissioned to form a project task force to manage and maintain the BESREMi® drug safety data database, assist in drug safety information collection/processing/exchange, and handle notifications to regulatory authorities in various countries.

The personnel dedicated to pharmacovigilance at PharmaEssentia Headquarters and each subsidiary or region hold regular meetings every other week with commissioned research institutions to ensure the proper implementation of the drug safety information collected from around the world and the reporting system. In 2022, a total of 22 meetings were held to track and manage the pharmacovigilance mechanism. In March 2022, we submitted the third periodic safety update report (PSUR) for BESREMi® after its launch to Taiwan's FDA, and there were no adverse drug events reported for the marketed drug. In addition, Tirbanibulin, authorized by Athenex, was granted a drug license by PharmaEssentia in 2022, and we will submit PSURs annually until 2028 in accordance with regulations.

Taiwan's Adverse Drug Reaction Reporting Mechanism

In the event of a serious adverse reaction to a marketed drug under normal use, the following channels can be used to report it:

- Healthcare professionals and the public can fill out the "Marketed Drug Adverse Reaction Reporting Form" and report it online after applying for an account or report it via email (adr@tdrf.org.tw)
- Pharmaceutical companies can report it online through the system by selecting the "Marketed Drug Adverse Reaction Reporting Form" and submitting it when completed
- Upon receiving relevant reports, PharmaEssentia will follow the "Guidelines for Completing Marketed Drug Adverse Reaction Reporting Forms" and report it through the online reporting system (https://adr.fda.gov.tw) or by sending the completed reporting form to the ADR center's email (adr@tdrf.org.tw)

BESREMi® Safety Monitoring in the United States

The US subsidiary uses a third-party logistics provider that meets quality requirements to submit transaction history records (TH), transaction information (TI), and transaction statements (TS) in accordance with the Drug Supply Chain Security Act (DSCSA) and related regulations for drug tracing. It also has a dedicated reporting management center, the PEC U.S. Call Center, which is managed by the US subsidiary's medical affairs team and is responsible for handling drug quality and safety-related demands and reporting messages from all sectors. In terms of product traceability, drug serialization was completed in 2020, and there were no drug recalls due to adverse events in 2022

Pharmacovigilance Training

100%

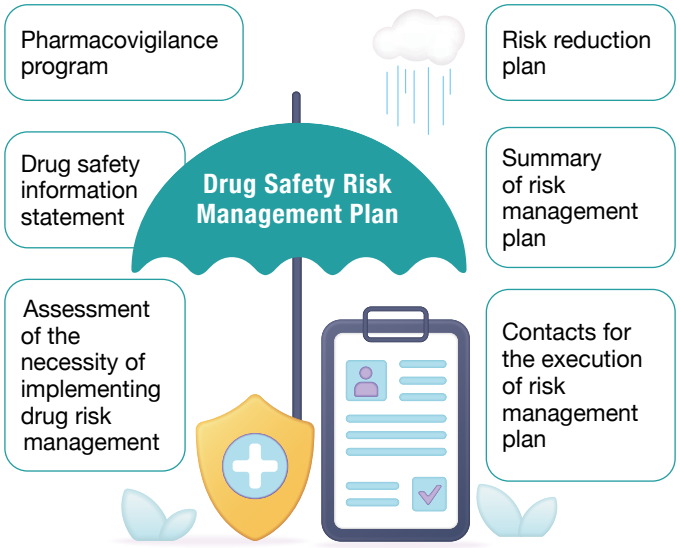
Completion rate of pharmacovigilance training for new employees

In accordance with pharmacovigilance regulations, PharmaEssentia's commissions external research organizations to develop and implement pharmacovigilance management and regulatory reporting plans. The company also regularly conducts pharmacovigilance training for all employees and keeps records of all training. In 2022, 11 company-wide annual pharmacovigilance training sessions were held, and new employees received pharmacovigilance training within one month of their start date, with a completion rate of 100%.

Training Types		Description
Outsourced	Domestic Training	Employees can choose to participate in drug safety training courses/seminars organized by domestic training institutions or regulatory agencies, with the education and training budget prepared by the department
	Overseas Training	To learn about the latest developments in our field and skills concerning drug safety as well as cultivate talents, the company sends personnel to participate in education and training courses organized by overseas institutions according to the company's needs
Internal	Pre-job Training	When new employees start their jobs, training related to drug safety reporting is conducted, and the training hours and course information are recorded
	Other Internal Training	To enhance employees' professional knowledge and skills in drug safety, drug safety reporting related training is conducted every year

Drug Safety Risk Management

In order to assess the safety risks of drugs after they are marketed, PharmaEssentia has adopted a standard operating procedure for drug safety risk assessment developed by an outsourced research institution, and commissioned the development of a risk management plan. Depending on the requirements of each country's regulations on pharmacovigilance management, a Drug Risk Management Plan is developed to comply with the country's regulations. After the product is launched, clinical data is collected to assess whether long-term use of the drug by patients will result in chronic side effects, which serves as the basis for the drug risk-benefit assessment. The results of the 2022 periodic safety report showed that no new safety information would affect the safety of BESREMi®. In 2023, PharmaEssentia will continue to collect safety information from all countries where BESREMi® is marketed to update the periodic safety report and evaluate the risk-benefit of BESREMi®.



Product Traceability Mechanism

SASB HC-BP-260a.1

PharmaEssentia has established a product traceability mechanism for its global supply chain, in which the batch number, lot number and factory activity records of each batch of drugs are kept to keep track of batch flow and ensure traceability. Currently, drug serialization has been implemented to regulate the packaging and serialization at processing plants to which we have outsourced work, achieving our purpose of having fully traceable individual product flows and usage records. BESREMi® sold in the United States has also been fully serialized, and qualified US filling contractors follow relevant regulations of the FDA's Drug Supply Chain Security Act (DSCSA) to carry out drug packaging and serialization, ensuring drug quality and safety.

Drug Recall Mechanism

SASB HC-BP-260a.2

0 Case

No incidents of adverse drug recall in 2022

PharmaEssentia has established a Return and Recall Procedure Manual to clearly define the product traceability system and improve the drug recall mechanism. In the event of product quality concerns, the drug recall can be completed quickly and effectively, providing an added level of safety for patients. The company also conducts annual recall simulation training to ensure accuracy and proficiency in the recall process. There were no incidents of drug recalls due to adverse drug events in 2022.