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SPECIFIC-INDUSTRY ESG STANDARD ALIGNING: SASB STANDARD COMPLIANCE CASE STUDY OF PT BIO FARMA

PENYELARASAN STANDAR ESG INDUSTRI SPESIFIK: STUDI KASUS KEPATUHAN STANDAR SASB DI PT BIO FARMA

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ABSTRACT

The study identifies critical gaps in Bio Farma's ESG reporting practices, particularly in the context of sustainability metrics under the Global Reporting Initiative (GRI) standards, which were deemed insufficient by stakeholders and regulatory audits. To address these challenges, this research proposes transitioning to the Sustainability Accounting Standards Board (SASB) Biotechnology & Pharmaceuticals standard to improve alignment with investor expectations and industry–specific benchmarks. The study employs a two-pronged methodology: gap analysis and benchmarking analysis. The gap analysis identifies unreported or insufficiently reported SASB metrics across environmental, social, and governance dimensions. Benchmarking analysis examines industry-leading companies' ESG reporting practices to derive actionable solutions that align Bio Farma with investor expectations and industry-specific financial materiality. Findings highlight significant discrepancies in areas such as clinical trial safety, affordability and pricing transparency, product traceability, and counterfeit drug management. Best practices from leading global pharmaceutical firms suggest robust reporting frameworks, enhanced data transparency, and a focus on quantifiable performance metrics. Based on these insights, the thesis proposes solutions for Bio Farma to close the reporting gaps, optimize SASB-aligned disclosure, and improve their reputation and accountability among investors and stakeholders.
Keywords: *ESG Reporting, SASB Standards, Gap Analysis, Benchmarking, Pharmaceutical Industry, Bio Farma, Sustainability Metrics.*

ABSTRAK

Penelitian ini mengidentifikasi kesenjangan kritis dalam praktik pelaporan ESG Bio Farma, terutama dalam konteks metrik keberlanjutan di bawah standar Global Reporting Initiative (GRI), yang dianggap kurang memadai oleh para pemangku kepentingan dan audit regulator. Untuk mengatasi tantangan-tantangan ini, penelitian ini mengusulkan transisi ke standar Sustainability Accounting Standards Board (SASB) Bioteknologi & Farmasi untuk meningkatkan keselarasan dengan ekspektasi investor dan tolok ukur khusus industri. Penelitian ini menggunakan metodologi dua cabang: analisis kesenjangan dan analisis pembandingan. Analisis kesenjangan mengidentifikasi metrik SASB yang tidak dilaporkan atau kurang dilaporkan di seluruh dimensi lingkungan, sosial, dan tata kelola. Analisis benchmarking mengkaji praktik pelaporan LST perusahaan-perusahaan terkemuka di industri untuk mendapatkan solusi yang dapat ditindaklanjuti yang menyelaraskan Bio Farma dengan ekspektasi investor dan materialitas keuangan spesifik industri. Temuan-temuan menyoroti perbedaan yang signifikan di berbagai bidang seperti keamanan uji klinis, keterjangkauan dan transparansi harga, ketertelusuran produk, dan manajemen obat palsu. Praktik terbaik dari perusahaan farmasi global terkemuka menyarankan kerangka kerja pelaporan yang kuat, transparansi data yang lebih baik, dan fokus pada metrik kinerja yang terukur. Berdasarkan wawasan ini, tesis ini mengusulkan solusi bagi Bio Farma untuk menutup kesenjangan pelaporan, mengoptimalkan pengungkapan yang selaras dengan SASB, serta meningkatkan reputasi dan akuntabilitas mereka di antara para investor dan pemangku kepentingan.
Kata Kunci: Pelaporan ESG, Standar SASB, Analisis Kesenjangan, Benchmarking, Industri Farmasi, Bio Farma, Metrik Keberlanjutan.

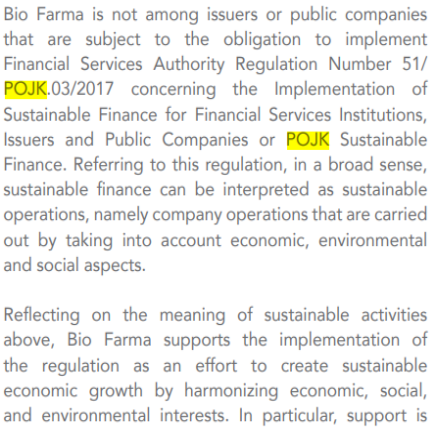
INTRODUCTION

In recent years, Environmental, Social, and Governance (ESG) criteria have captured a central focus for businesses across sectors, with the pharmaceutical industry facing scrutiny because of its critical role in public health and environmental impact. In

Indonesia, there has been a growing concern focusing on ESG among businesses, governments, and academia, citizens, regulators, and media, which put pressures on companies to address those three pillars of sustainability responsibly. One of major milestone is the issuance of *Aspirasi Pemegang Saham/Menteri Untuk Penyusunan Rencana Kerja dan Anggaran Perusahaan Tahun 2025* or Shareholders' or Minister's Aspirations for the Preparation of the 2025 Corporate Work Plan and Budget which mentioned that every State-Owned Enterprise should adopt ESG aspects as critical factors to achieve sustainable value for State Owned Enterprise companies. The ESG adoption is expected to address 1) The environmental issues on a company's operation including the suppliers or partners activities which impact the environment. Environmental issues include climate changes, air pollution, waste, and biodiversity, 2) The social issues on companies which impact the social actions including staff regulation, workforce infestation, products, community impact, and organizations culture, 3) The governance issues on companies which measure the quality and decision making, governance, and responsibility distribution including business ethics, resources allocation, governance structure, and external advocacies.

In the pharmaceutical industry, ESG has become especially pertinent as companies navigate challenges related to environmental footprint, ethical considerations, and social impacts. Furthermore, the Paris Agreement that was signed by 196 countries mandated every country to implement Nationally Determined Contributions (NDCs) outlining their emissions reduction plans, which pressed corporations to reduce their emissions in order to meet climate goals. Indonesia's commitments to the Paris Agreement is undeniable, and Bio Farma, known for high energy consumptions and emissions should adopt a greener operational business, adopt energy-efficient practices, reduce their carbon footprints, and explore more green alternatives. The United Nations also issued a global framework for sustainable development by 2030 called Sustainable Development Goals (SDGs) in 205, which outline 17 goals to address poverty, education, health, and climate action. As a pharmaceutical company, Bio Farma should focus on achieving SDG number 3 (Good Health and Well-being) and Goal 13 (Climate Action), because they have significant environmental responsibilities on their operation.

Moreover, Indonesia's minister of environment issued regulation no. 03/2014 on environmental monitoring and management, which mandate companies to monitor their environmental impact within their organization, especially those who produce significant environmental impacts. *Otoritas Jasa Keuangan (OJK)*, or Financial Services Authority also issued OJK regulation No. 51/POJK.03/2017 on sustainable finance, which encourages sustainability finance reporting for public companies. Even though Bio Farma is not a public company, this regulation is important for them to guide them in integrating sustainable practices into their operations. They mentioned that this regulation is mandatory for them to create sustainable economic growth by harmonizing economic, social, and environmental interests.



Bio Farma is not among issuers or public companies that are subject to the obligation to implement Financial Services Authority Regulation Number 51/ POJK.03/2017 concerning the Implementation of Sustainable Finance for Financial Services Institutions, Issuers and Public Companies or POJK Sustainable Finance. Referring to this regulation, in a broad sense, sustainable finance can be interpreted as sustainable operations, namely company operations that are carried out by taking into account economic, environmental and social aspects.

Reflecting on the meaning of sustainable activities above, Bio Farma supports the implementation of the regulation as an effort to create sustainable economic growth by harmonizing economic, social, and environmental interests. In particular, support is

Figure 1. Bio Farma Adoption on *POJK* Regulation *No. 51/POJK.03/2017*
Source: Bio Farma Sustainability Report, 2023

As the Financial Services Authority Regulation or *Otoritas Jasa Keuangan (OJK)* Number 51/POJK.03/2017 on Implementation of Sustainable Finance for Financial Service Institutions, Issuers, and Public Companies, and Circular Letter of the Financial Services Authority Number 16/SEOJK.04/2021 on the Form and Content of Annual Report of Issuer or Public Companies, Bio Farma issued their sustainability report each year using the GRI standards 2021.

Describing the investor perspective in ESG, over years, sustainable and impact investing have become a prevalent criteria in investing strategies. Raghvarendra Rau and Ting Yu (2022) mentioned some of the ESG investing approaches including ESG integration, corporate engagement and shareholder action, norms-based screening, negative/ exclusionary screening, best-in-class/positive screening, sustainability themed/thematic investing, impact investing and community investing.

Strategy	Description
ESG integration	The systematic and explicit inclusion by investment managers of ESG factors into financial analysis
Corporate engagement and shareholder action	Employing shareholder power to influence corporate behaviour, including through direct corporate engagement such as communicating with senior management and/or boards of companies, filing or co-filing shareholder proposals and proxy voting that is guided by comprehensive ESG guidelines
Norms-based screening	Screening of investments against minimum standards of business or issuer practice based on international norms such as those issued by United Nations, OECD and NGOs
Negative/exclusionary screening	The exclusion from a fund or portfolio of certain sectors, companies, countries, or other issuers based on activities considered not investable. Exclusion criteria based on norms and values can refer to product categories such as weapon, tobacco, gaming, etc. company practices such as animal testing, violation of human rights and corruption, or controversies
Best-in-class/positive screening	Investment in sectors, companies, or projects selected for positive ESG performance relative to industry peers and that achieve a rating above a certain threshold
Sustainability themed/ thematic investing	Investing in themes or assets specifically contributing to sustainable solutions – environmental and social – such as sustainable agriculture, green buildings, lower carbon tilted portfolio, gender equity and diversity
Impact investing and community investing	Impact investing refers to investing to achieve positive, social and environmental impacts. It requires measuring and reporting against these impacts, demonstrating the intentionality of investor and underlying asset/investee and demonstrating the investor contribution Community investing is where capital is specifically directed to traditionally underserved individuals or communities, as well as financing that is provided to businesses with a clear social or environmental purpose. Some community investing is impact investing, but community investing is broader and considers other forms of investing and targeted lending activities

Figure 2. ESG Investing Approach Strategy
Source: Rau and Yu, 2022

The figure above (Impact investing and community investing strategy) highlights the importance of ESG reporting, which requires measuring and reporting against these impacts, demonstrating the intentionality of the investor and underlying asset and demonstrating the investor contribution. This means that investors prefer a measurable report showing the information of financial materiality. The Norm-based screening strategy also highlights the importance of sustainability standards, which screen the investment based on minimum standard of business or issuer practice of international norms. The Negative/exclusionary screening and Best-in-class/positive screening also describe the investment strategy based on certain sectors, viewing from the industry sector that have positive ESG performance relative to the same industry, above the certain threshold. This means that screening companies based on its industry is necessarily needed, in which the investors can compare a certain company ESG performance relative to its competitors, providing a meaningful assessment of how good that company is.

In selecting the ESG framework, companies should consider which metrics that are most suitable within their organization, to publicly commit to it and report to the public. The company may select factors which are the most material to their business, and the audience of the report itself. The audience may vary from stakeholders, regulators, investors, and the public. They should know what is the objective of their ESG report with the right audience, along with the commitment of transparency and accountability, and completeness.

METHOD

This research is a qualitative research which captures secondary data as the base of the analysis in which then primary data taken as the meaningful support to validate the analysis. The research undertakes a qualitative approach which investigates the SASB Biotechnology and Pharmaceuticals metrics gaps, in case study design. Herdiansyah (2010) mentioned that the characteristics of qualitative research is flexible, and within flexibility, the research can change according to existing situations and conditions. While case studies investigate specific phenomena within bounded contexts, allowing for a comprehensive understanding of complex issues (Gustafsson, 2024). In addition, case study research implements systematic data collection and analysis often utilizing software or tools for rigorous examination (Cherkaoui & Oudrhough, 2024). Case study focuses more on in-depth analysis of real-life cases in contextual settings, which in this case

Case studies have been discussed intensively in literature; but there is no strong reference regarding the specific steps one may use to conduct case study research effectively (Hancock & Algozzine, 2016). Although there is no specific steps or protocol to follow in case study research, the author tries to undertake the research in a practical guideline, to execute the case study along with the application to conduct the research. The guideline involves defining company business issues' case, defines research questions and objectives, literature review, data collection and interpretation mainly from sustainability and annual report documents along with primary data from stakeholders, investigating the gaps of SASB metric as data analysis process, formulating for improvements, and

conclusion drawing. with recommendations. Figure III.1 depicts the guideline or research framework of this case study research.

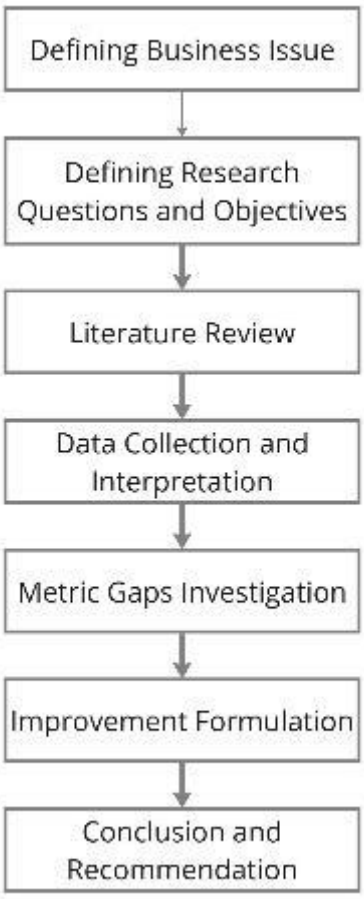


Figure 3. Research Guideline/Framework
Source: Author, 2024

The guideline above is a structured framework in conducting this research. The first thing to do is define the specific business issue, which later the research question and objectives can be generated. Then literature review is conducted as a process to explore previous related research, gaps in knowledge, and strengthen the direction of the research. After getting a clear vision of the research, data then collected both secondary and primary from various sources, mainly from annual and sustainability reports as secondary data and interviews as primary data. After identifying all gaps, then formulation of gaps related improvement can be undertaken. And the last, the research conclusion and recommendations can be generated for this case study research, and future related research.

RESULT AND DISCUSSION

Ethical Marketing

HC-BP-270a.1. Total amount of monetary losses as a result of legal proceedings associated with false marketing claims

The entity must disclose the total monetary losses incurred during the reporting period due to legal proceedings related to false marketing claims. These

proceedings can involve any adjudicative process, whether before a court, regulator, arbitrator, or other legal body. The losses must include all monetary liabilities to the opposing party or others, such as settlements, verdicts, fines, civil judgments, regulatory penalties, disgorgement, restitution, or criminal penalties. However, legal and defense-related fees should not be included in the loss calculation. The disclosure should also encompass legal proceedings related to the enforcement of applicable laws and regulations. Additionally, the entity must provide a brief description of the nature and context of the legal proceedings, including whether the outcome was a judgment, settlement, guilty plea, or deferred prosecution. Finally, the entity must describe any corrective actions taken in response to the legal proceedings, such as changes in operations, management, products, business partners, training, or technology.

However, there is no data reported regarding the amount of monetary losses of legal proceedings associated with false marketing claims and hence this metric is classified as "Not Complete".

HC-BP-270a.2. Description of code of ethics governing promotion of off-label use of products

The entity must describe the aspects of its code of ethics related to ethical marketing and the promotion of off-label use of products, including how the code defines "off-label promotion." If the entity uses a corporate policy, code of conduct, guideline, or contractual terms similar in intent to a code of ethics, these should be considered equivalent for this purpose. The entity is also required to outline the mechanisms it has implemented to ensure compliance with the code, which may include disciplinary actions for violations, training programs, internal audits, regulatory review committees, and details about the degree and frequency of the training provided.

As a company which adopts Good Corporate Governance (GCG), Bio Farma has implemented their own Code of Conduct which is used as reference for company organs and personnel in applying business values and ethics which ruled in *Peraturan Bersama Dewan Komisaris dan Direksi PT Bio Farma (Persero) No. PER-08/DK/BF/12/2018, No. PER-06965/DIR/ XII/2018 tanggal 31 Desember 2018 tentang Pedoman Perilaku PT Bio Farma (Persero)* and *KEP-06/DK/BF/04/2021, Nomor: PER-003.01/DIR/IV/2021 tentang Pedoman Perilaku (Code of Conduct) tanggal 1 April 2021*. Their code of conduct covers comprehensive ethical values as the basis for the company's policy and cultural direction, that includes their business ethics and work ethics.

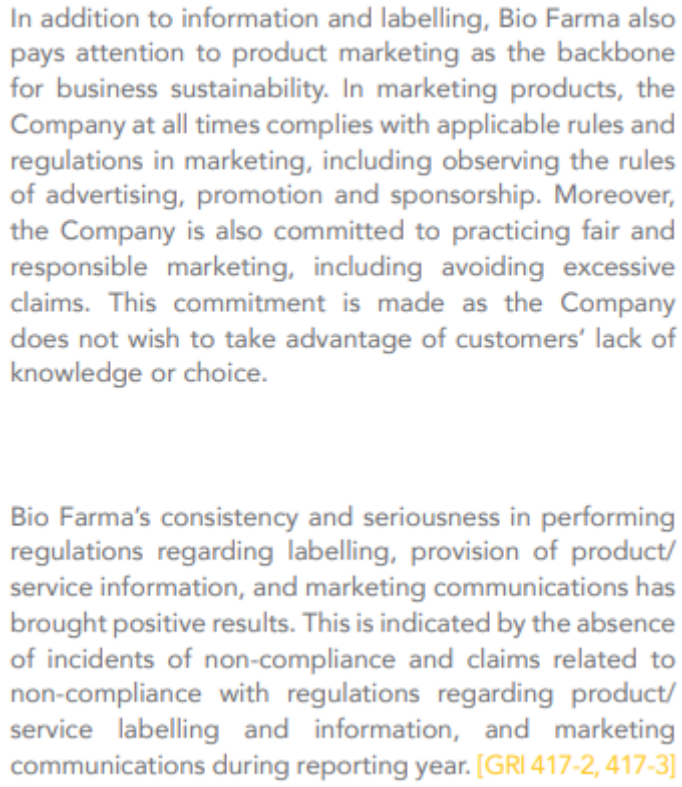

Business Ethics regulates the standards of behavior in interacting and dealing with stakeholders:
1. Relationship with Employees
2. Relationship with Customers
3. Relationship with Suppliers / Business Partners
4. Relationship with Creditors
5. Relationship with Competitors
6. Ethics towards Mass Media
7. Relationship with the Government
8. Relationship with Community and the Environment
9. Relationship with Shareholders
10. Relationship with Joint Venture Subsidiaries
11. Relationship with Professional Organizations
12. Relationship with Health Professionals (ASN) and Private Employees

Work Ethics regulates the standards of behavior for Bio Farma's employees in carrying out work and interacting:
1. Compliance with Law
2. Concern for Occupational Health and Safety and Environmental Conservation
3. Intellectual Property
4. Political Activation
5. Providing Gifts, Meals, Entertainment, Donations and Other Facilities
6. The Recording and Preparation and Integration of Financial Reports
7. Sponsorship for Health Professions
8. Respect for Human Rights
9. The Protection of Company Information
10. Immoral Behavior, Abuse of Drugs and Illegal Drugs, Gambling and the Use of Firearms
11. Equal Opportunities to Get a Job and Profession
12. The Protection of Company Assets
13. The Use of Social Media
14. Promotion or Advertisement

Figure 4. Labeling Regulation Description

Source: Bio Farma Sustainability Report page 303, 2023

On the other hand, through their sustainability report 2023 page 303, they actually have a statement regarding the promoting and label use of products, which they ensure that Bio Farma performs consistent regulations of labelling, provision of products information, and marketing communications as can be seen below.


In addition to information and labelling, Bio Farma also pays attention to product marketing as the backbone for business sustainability. In marketing products, the Company at all times complies with applicable rules and regulations in marketing, including observing the rules of advertising, promotion and sponsorship. Moreover, the Company is also committed to practicing fair and responsible marketing, including avoiding excessive claims. This commitment is made as the Company does not wish to take advantage of customers' lack of knowledge or choice.

Bio Farma's consistency and seriousness in performing regulations regarding labelling, provision of product/ service information, and marketing communications has brought positive results. This is indicated by the absence of incidents of non-compliance and claims related to non-compliance with regulations regarding product/ service labelling and information, and marketing communications during reporting year. [GRI 417-2, 417-3]

Figure 5. Labeling Regulation Description
Source: Bio Farma Sustainability Report page 303, 2023

And based on the interview interpretation, Bio Farma does not implement a code of ethics regarding off-label use of products. They indeed have a white-label production that a specific product might be sold to strict-regulated business partners worldwide, but still they have no off-label use of products code of ethics. Because of mentioned reasons and data, the code of conduct and their commitment on performing a strict regulation regarding labelling and product information does not explain further about off-label use of products, while they address ethical marketing and promotion through their work ethics number 14. Furthermore, they should describe ethical marketing especially regarding the off-label use of products based on their work ethics, in addressing this metric. Because of this reason, this metric is classified as "Not Strong Policy".

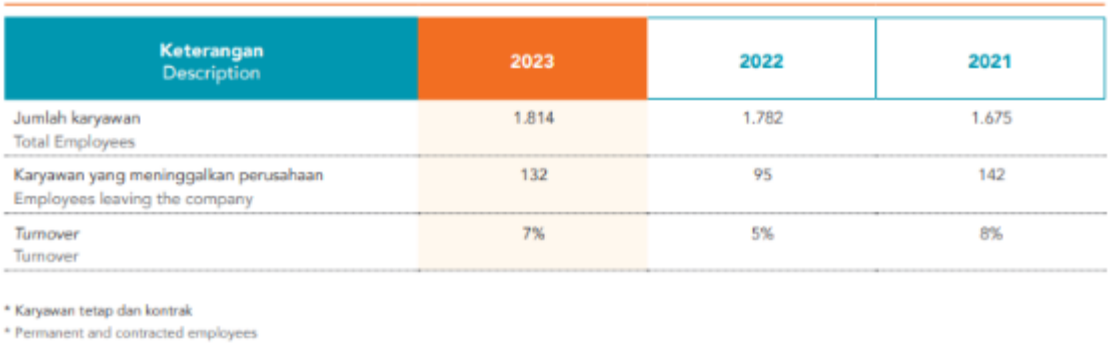
Employee Recruitment, Development & Retention

HC-BP-330a.1. Discussion of talent recruitment and retention efforts for scientists and research and development staff

The entity must describe its strategy for attracting and retaining talent, particularly scientists and staff directly involved in research and development (R&D) for new biopharmaceutical products. This strategy may include initiatives such as mentorship programs, career development opportunities, leadership training, and incentive structures. The entity may also provide detailed descriptions of its recruitment and retention programs, focusing on an overview of the initiatives, their implementation, levels of participation, and metrics that demonstrate their effectiveness. These disclosures should highlight how the entity fosters a supportive and growth-oriented environment for R&D personnel, showcasing efforts to build a skilled and motivated workforce.
As can be seen in their sustainability report 2023 pages 244 to 254, Bio Farma has already stated a clear description of their talent recruitment and retention efforts as their strategy including employee competency development, training plan and employee remuneration and welfare. The recruitment and retention programs, followed the Diversity, Equity and Inclusion (DEI) principle which the search and selection process considers the diversity, equality and inclusion to represent various groups of people with the help of various recruitment media channels such as *portal BUMN (Rekrutmen Bersama BUMN & Magang Generasi Bertalenta),* companies job portal, and career development centers in various universities and other media. Even Though they do not explain particular scientists and research and development staff, the information considered as a complete information which makes this metric is classified as "Available".

HC-BP-330a.2. (1) Voluntary and (2) involuntary turnover rate for: (a) executives/senior managers, (b) mid-level managers, (c) professionals, and (d) all others

The entity must disclose the voluntary and involuntary employee turnover rates as percentages across four employee categories: executives/senior managers, mid-level managers, professionals, and all other employees. Executives/senior managers are defined as those responsible for strategy, policy formulation, and organizational direction. Mid-level managers oversee the delivery of functions, services, or products at group, regional, or divisional levels. Professionals execute specialized tasks requiring professional degrees or certifications, while all others include employees outside these classifications. The entity may use the International Standard Classification of Occupations (ISCO) or relevant jurisdictional standards to define these categories and should specify the classification system used. Voluntary turnover is calculated as the percentage of employee-initiated separations (e.g., resignations, retirements) divided by the average number of employees during the reporting period. Involuntary turnover is similarly calculated for separations initiated by the entity (e.g., dismissals, downsizing, or contract non-renewals). In the same section of Human Resources Development Strategy (Sustainability report 2023, page 245), the turnover rate both voluntary and involuntary are released clearly based on the age group and gender, the reasons for leaving and total turnover rate as below.



Keterangan Description	2023	2022	2021
Jumlah karyawan Total Employees	1.814	1.782	1.675
Karyawan yang meninggalkan perusahaan Employees leaving the company	132	95	142
Turnover Turnover	7%	5%	8%

* Karyawan tetap dan kontrak
* Permanent and contracted employees

Figure 6. Turnover Rate by Year
Source: Bio Farma Sustainability Report page 245, 2023

However, the data provided is not disclosing the employee categories: executives/senior managers, mid-level managers, professionals, and all other employees, and hence make the metric criteria not completed. For this reason, however, this metric is classified as "Not Complete" due to lack of employee turnover rate data based on the employee categories.

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 programme or equivalent third-party audit programmes for integrity of supply chain and ingredients

The entity must disclose the percentage of its facilities and its Tier I suppliers' facilities participating in the Rx-360 International Pharmaceutical Supply Chain Consortium audit program or an equivalent third-party audit program. Equivalent programs are those conducted by external auditors with comparable standards for supply chain and ingredient integrity. The disclosure includes facilities owned or operated by the entity, with the percentage calculated as the number of participating facilities divided by the total number of the entity's facilities. Similarly, the entity must disclose the percentage of Tier I suppliers' facilities, limited to those with which it directly transacts and optionally focused on suppliers accounting for at least 90% of its spending. This percentage is calculated as the number of participating Tier I suppliers' facilities divided by the total number of such facilities.

Bio Farma do conducted an internal audit program which audits the environmental and social assessment or criteria to their supplier through their General Terms and Conditions (GTC) for Procurement of Goods/Services at Bio Farma.

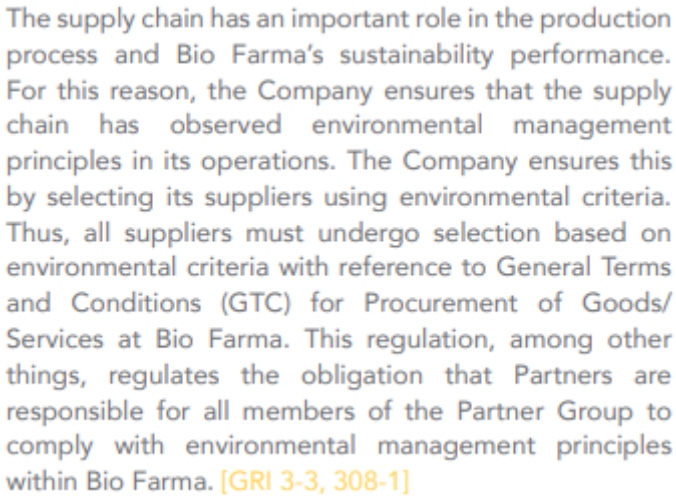

The supply chain has an important role in the production process and Bio Farma's sustainability performance. For this reason, the Company ensures that the supply chain has observed environmental management principles in its operations. The Company ensures this by selecting its suppliers using environmental criteria. Thus, all suppliers must undergo selection based on environmental criteria with reference to General Terms and Conditions (GTC) for Procurement of Goods/ Services at Bio Farma. This regulation, among other things, regulates the obligation that Partners are responsible for all members of the Partner Group to comply with environmental management principles within Bio Farma. [GRI 3-3, 308-1]

Figure 7. Supplier Selection Description
Source: Bio Farma Sustainability Report page 209, 2023

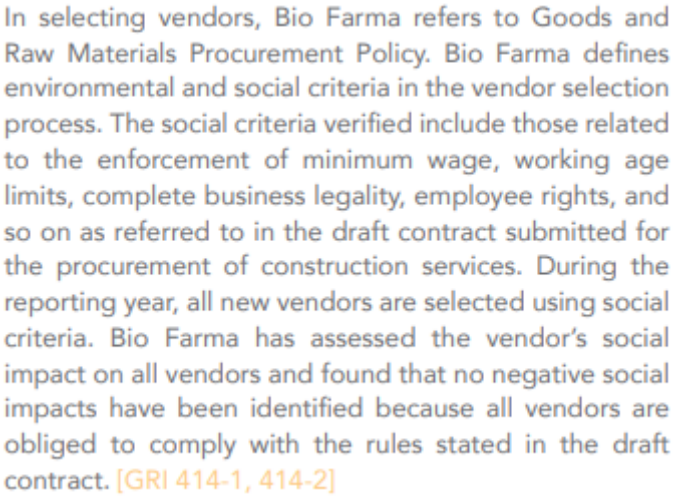

In selecting vendors, Bio Farma refers to Goods and Raw Materials Procurement Policy. Bio Farma defines environmental and social criteria in the vendor selection process. The social criteria verified include those related to the enforcement of minimum wage, working age limits, complete business legality, employee rights, and so on as referred to in the draft contract submitted for the procurement of construction services. During the reporting year, all new vendors are selected using social criteria. Bio Farma has assessed the vendor's social impact on all vendors and found that no negative social impacts have been identified because all vendors are obliged to comply with the rules stated in the draft contract. [GRI 414-1, 414-2]

Figure 8. Supplier Selection Description
Source: Bio Farma Sustainability Report page 119, 2023

However, their solely internal auditing does not match with this metric criteria, which demand third-party audit programmes for integrity of supply chain and ingredients. Moreover, Bio Farma did not release any data on the percentage of the audit conducted, and by that metric is classified as "Not Complete".

Business Ethics

HC-BP-510a.1 Total amount of monetary losses as a result of legal proceedings associated with corruption and bribery

The entity must disclose the total monetary losses incurred during the reporting period from legal proceedings related to bribery and corruption. These proceedings may include adjudications before courts, regulators, arbitrators, or other legal bodies. The disclosed losses must cover all monetary liabilities to opposing parties or others, resulting

from settlements, verdicts, fines, civil judgments, regulatory penalties (e.g., disgorgement or restitution), and criminal penalties incurred during the reporting period. Legal defense costs, such as fees and expenses, are excluded from the calculation. The scope includes legal proceedings associated with jurisdictional law or regulatory enforcement. The entity should also briefly describe the nature and context of these losses, such as judgments, settlements, guilty pleas, or deferred prosecution agreements, specifically in relation to bribery or fraud. Additionally, the entity must detail any corrective actions taken in response to these legal proceedings, which may include operational changes, management adjustments, process improvements, revisions in dealings with business partners, enhanced training, or adoption of new technologies.

Bio Farma through their annual report page 633 has already listed their legal proceeding issues, which show a complete material regarding each issue, including the plaintiff, the defendant, the subject, risks faced by the company, the nominal value of lawsuits, the follow up, and the status. Bio Farma itself has not had any lawsuit occurring, but the subsidiaries which are Kimia Farma and Indofarma have legal issues occurings.

The State Audit Agency (BPK) has conducted a Compliance Audit on Revenue, Expenses, and Investment Activities from 2020 to the first half of 2023 at PT Indofarma Tbk, its subsidiaries, and related institutions, followed by an investigative audit, the report of which was submitted to the Attorney General on May 20, 2024. The group has already followed up on BPK's recommendations, particularly concerning the recovery of assets from all parties who illegally benefited from the Company's assets as stated in the BPK report. As of the report issuance date, a portion of the recovered funds amounting to Rp31,936,250 has been credited to the group's account. The group is now awaiting the court's decision regarding the Investigative Audit Report submitted by BPK to the Attorney General.

Figure 9. Indofarma Legal Issue

Source: Bio Farma Annual Report section Financial Report page 272, 2023

INAF is currently facing a legal case regarding for Debt Payment Obligation Suspension Lawsuit (PKPU) with case number 144/Pdt.Sus-PKPU/2024/ PN.Niaga.Jkt.Pst dated May 8, 2024. At present, the PKPU case is being handled by the Commercial Court of Central Jakarta and the invoices have been registered, currently undergoing verification by the PKPU Administration Team. Thus, the legal case related to the invoices from PT Era Medika Alkensindo, PT Medihop, PT Emjebe Pharma, PT Distriversa Buanamas, PT Distributor Bersama Nusantara, PT Merapi Utama Pharma, PT Widatra Bhakti, PT Kalmed Manufaktur Indonesia, PT Permana Putra Mandiri, PT Tiga Pilar Sejahtera, BPR Intidana, and PT Bank Perkreditan Rakyat Universal will be resolved through this PKPU process.

Figure 10. Indofarma Legal Issue

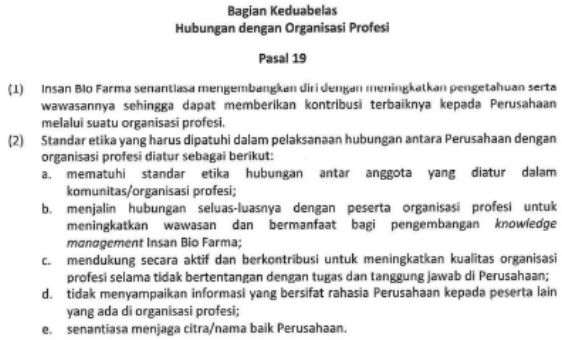
Source: Bio Farma Annual Report section Financial Report page 272, 2023

Based on the data, legal issues associated with corruption and bribery consists of two issues, which first is the *Badan Audit Keuangan (BPK)* audit of compliance audit on revenue, expenses, and investment activities from 2020 to the first half of 2023 of Indofarma, of illegal benefit of some parties taken of the company assets. The company lost Rp. 31.936.250 and has been credited to the *BPK'*s account. On the other hand Indofarma is also facing another legal case regarding PKPU related to the invoices from several company parties, which strongly identified as a corruption act. In this case alone, they have lost Rp. 6.000.000.000 which they already paid by 50%. This disclosure of total monetary losses makes this metric classified as "Completed" for Bio Farma.

HC-BP-510a.2. Description of code of ethics governing interactions with healthcare professionals

The entity must describe the aspects of its code of ethics that govern interactions with healthcare professionals, including individuals or entities involved in providing health care services (e.g., physicians, pharmacists, nurses) or those influencing the use or purchase of its products (e.g., purchasing agents, practice managers, and group purchasing organizations). The disclosure should address the content of the code, such as policies on food and entertainment, training, education, and participation in formulary committees, as well as its scope, including the types and percentages of staff it applies to. Corporate policies, codes of conduct, guidelines, or contractual terms with similar intent may also be included. The entity should discuss the mechanisms ensuring compliance, such as enforcement actions, inspections, compliance review committees, implementation of corrective actions for violations, and details on the degree and frequency of training programs. If the entity uses a second- or third-party code of ethics, it may reference the code without detailing its content.

In this metric, Bio Farma has already implement a code of conduct embedded in their Good Corporate Governance (GCG) which obey the *Peraturan Bersama Dewan Komisaris dan Direksi PT Bio Farma (Persero) Nomor: KEP-06/DK/BF/04/2021, Nomor: PER-003.01/DIR/IV/2021 tentang Pedoman Perilaku (Code of Conduct) tanggal 1 April 2021,* in which the code of conduct includes the description governing interactions with healthcare professionals. The description can be seen in their code of conduct document (https://www.biofarma.co.id/media/file/originals/post/2024/09/17/code-of-conduct.pdf) *pasal* (clause) 19 and 20. In that document, the interactions with healthcare professionals and professional organizations are clearly defined and by that the metric is classified as "Available".



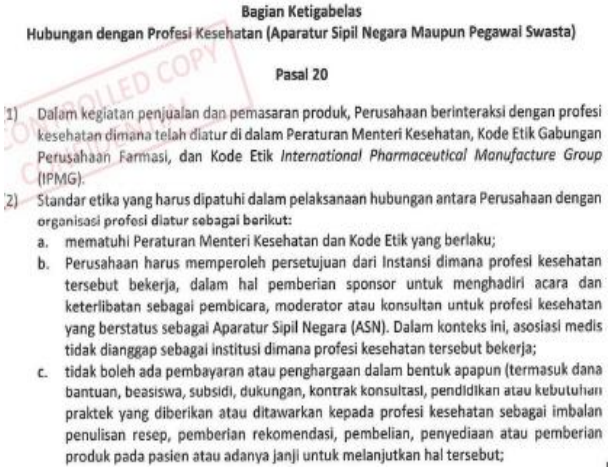
Bagian Keduabelas
Hubungan dengan Organisasi Profesi

Pasal 19

(1) Insan Bio Farma senantiasa mengembangkan diri dengan meningkatkan pengetahuan serta wawasannya sehingga dapat memberikan kontribusi terbaiknya kepada Perusahaan melalui suatu organisasi profesi.
(2) Standar etika yang harus dipatuhi dalam pelaksanaan hubungan antara Perusahaan dengan organisasi profesi diatur sebagai berikut:
   a. mematuhi standar etika hubungan antar anggota yang diatur dalam komunitas/organisasi profesi;
   b. menjalin hubungan seluas-luasnya dengan peserta organisasi profesi untuk meningkatkan wawasan dan bermanfaat bagi pengembangan *knowledge management* Insan Bio Farma;
   c. mendukung secara aktif dan berkontribusi untuk meningkatkan kualitas organisasi profesi selama tidak bertentangan dengan tugas dan tanggung jawab di Perusahaan;
   d. tidak menyampaikan informasi yang bersifat rahasia Perusahaan kepada peserta lain yang ada di organisasi profesi;
   e. senantiasa menjaga citra/nama baik Perusahaan.

Figure 11. Code of Conducts Governing Interactions with Healthcare Organizations

Source: Bio Farma Code of Conduct Document page 15, 2021



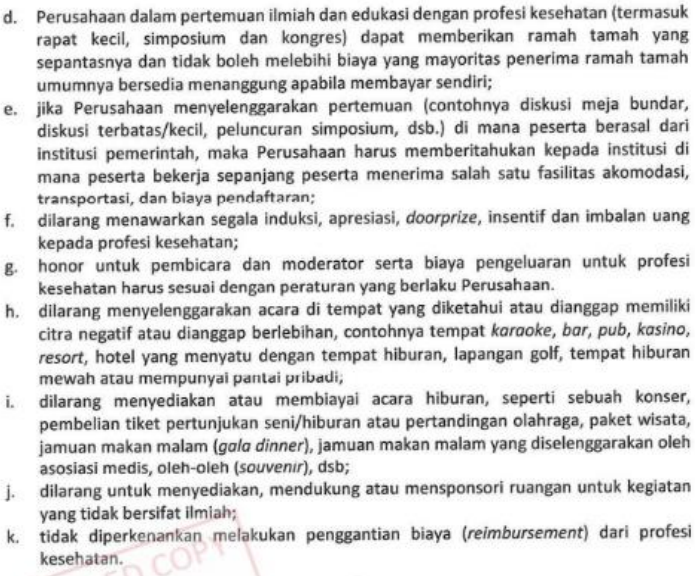
Bagian Ketigabelas
Hubungan dengan Profesi Kesehatan (Aparatur Sipil Negara Maupun Pegawai Swasta)

Pasal 20

1) Dalam kegiatan penjualan dan pemasaran produk, Perusahaan berinteraksi dengan profesi kesehatan dimana telah diatur di dalam Peraturan Menteri Kesehatan, Kode Etik Gabungan Perusahaan Farmasi, dan Kode Etik *International Pharmaceutical Manufacture Group* (IPMG).
2) Standar etika yang harus dipatuhi dalam pelaksanaan hubungan antara Perusahaan dengan organisasi profesi diatur sebagai berikut:
   a. mematuhi Peraturan Menteri Kesehatan dan Kode Etik yang berlaku;
   b. Perusahaan harus memperoleh persetujuan dari Instansi dimana profesi kesehatan tersebut bekerja, dalam hal pemberian sponsor untuk menghadiri acara dan keterlibatan sebagai pembicara, moderator atau konsultan untuk profesi kesehatan yang berstatus sebagai Aparatur Sipil Negara (ASN). Dalam konteks ini, asosiasi medis tidak dianggap sebagai institusi dimana profesi kesehatan tersebut bekerja;
   c. tidak boleh ada pembayaran atau penghargaan dalam bentuk apapun (termasuk dana bantuan, beasiswa, subsidi, dukungan, kontrak konsultasi, pendidikan atau kebutuhan praktek yang diberikan atau ditawarkan kepada profesi kesehatan sebagai imbalan penulisan resep, pemberian rekomendasi, pembelian, penyediaan atau pemberian produk pada pasien atau adanya janji untuk melanjutkan hal tersebut;

Figure 12. Code of Conducts Governing Interactions with Healthcare Professionals 1

Source: Bio Farma Code of Conduct Document page 15, 2021



d. Perusahaan dalam pertemuan ilmiah dan edukasi dengan profesi kesehatan (termasuk rapat kecil, simposium dan kongres) dapat memberikan ramah tamah yang sepantasnya dan tidak boleh melebihi biaya yang mayoritas penerima ramah tamah umumnya bersedia menanggung apabila membayar sendiri;
e. jika Perusahaan menyelenggarakan pertemuan (contohnya diskusi meja bundar, diskusi terbatas/kecil, peluncuran simposium, dsb.) di mana peserta berasal dari institusi pemerintah, maka Perusahaan harus memberitahukan kepada institusi di mana peserta bekerja sepanjang peserta menerima salah satu fasilitas akomodasi, transportasi, dan biaya pendaftaran;
f. dilarang menawarkan segala induksi, apresiasi, *doorprize*, insentif dan imbalan uang kepada profesi kesehatan;
g. honor untuk pembicara dan moderator serta biaya pengeluaran untuk profesi kesehatan harus sesuai dengan peraturan yang berlaku Perusahaan.
h. dilarang menyelenggarakan acara di tempat yang diketahui atau dianggap memiliki citra negatif atau dianggap berlebihan, contohnya tempat *karaoke*, *bar*, *pub*, *kasino*, *resort*, hotel yang menyatu dengan tempat hiburan, lapangan golf, tempat hiburan mewah atau mempunyai pantai pribadi;
i. dilarang menyediakan atau membiayai acara hiburan, seperti sebuah konser, pembelian tiket pertunjukan seni/hiburan atau pertandingan olahraga, paket wisata, jamuan makan malam (*gala dinner*), jamuan makan malam yang diselenggarakan oleh asosiasi medis, oleh-oleh (*souvenir*), dsb;
j. dilarang untuk menyediakan, mendukung atau mensponsori ruangan untuk kegiatan yang tidak bersifat ilmiah;
k. tidak diperkenankan melakukan penggantian biaya (*reimbursement*) dari profesi kesehatan.

Figure 13. Code of Conducts Governing Interactions with Healthcare Professionals 2

Source: Bio Farma Code of Conduct Document page 16, 2021

Activity Metric

HC-BP-000.A. Number of Patient Treated

This Metric demands the disclosure of patients treated in 2023 through the company's products. Bio Farma actually disclosed the total product batch released in 2023, which is 1.486 batch. But the total number of patients treated by this number of product releases is not reported. And by that, this metric is classified as "Not Completed".

HC-BP-000.B. Number of Drugs (1) in portfolio and (2) in research and development (Phases 1-3)

This metric demands the disclosure of the total number of drugs in portfolio and under research and development. Bio Farma has published their drugs product as can be seen in their sustainability report page 110 to 114, in total of 43 various drug products. But the disclosure of drugs under research and development phases 1-3 is not published, which make this metric classified as "Not Completed".

Business Solution

In this section will be explained the solutions addressing the Bio Farma alignment to SASB Biotechnology and Pharmaceutical standard. The solutions will address each metric which suggests Bio Farma to promote transparency relative to each metric. The solutions will focus to the unfinished metric disclosures, in which Bio Farma lack of. But notes apply, where Bio Farma may decide to not report some specific metric to confidentiality. List below will describe the solutions.

Safety of Clinical Trial Participants - Discussion, by region, of management process for ensuring quality and patient safety during clinical trials (HC-BP-210a.1)

This metric has no further description regarding the quality ensuring and patient safety during clinical trials. In addressing this issue, Bio Farma can start considering implementing a management process of quality assurance and patient safety during the clinical trials. Bio Farma can take a look at best practice to start implementing. Bio Farma suggested creating a special section in their website or their sustainability report which describes their management process regarding this metric.

Bio Farma should outline and publish its Standard Operating Procedures (SOPs) for clinical trial management, including risk mitigation strategies and safety measures, which also Provide regional data for each clinical trial site, detailing how Bio Farma ensures compliance with global safety protocols (e.g., Good Clinical Practices - GCP). Merck publishes a comprehensive breakdown of clinical trial management processes, explicitly mentioning audit protocols and safety systems in their SASB index. Bio Farma should adopt a similar practice, as it provides more detailed information among other companies.

Safety of Clinical Trial Participants - Number of inspections related to clinical trial management and pharmacovigilance that resulted in: (1) firm voluntary remediation or (2) regulatory or administrative actions taken against the firm (HC-BP-210a.2)

The result shows that this metric has no data reported by Bio Farma. In addressing this issue, Bio Farma should

monitor and report the total number of inspections (voluntary and regulatory) for clinical trial sites and pharmacovigilance activities, which can include both internal inspections and external audits. For best practice example, Pfizer discloses inspection outcomes and corrective actions taken for non-compliance. Bio Farma should replicate this level of transparency.

Safety of Clinical Trial Participants - Total amount of monetary losses as a result of legal proceedings associated with clinical trials in developing countries (HC-BP-210a.3)

Bio Farma should conduct a risk assessment of all clinical trials to identify potential legal liabilities, while adopt SASB's recommendation of disclosing monetary losses from legal proceedings, while protecting confidentiality where required. An example from GSK, which publicly reports material legal proceedings and their financial implications, demonstrating accountability to investors considered as the best practice among other companies in this metric

Affordability & Pricing - Percentage change in: (1) weighted average list price and (2) weighted average net price across product portfolio compared to previous reporting period (HC-BP-240b.2)

Develop a pricing transparency report that includes percentage changes in average list prices and weighted average net prices over time. Bio Farma can emulate practices from GSK and Pfizer, which provide clear disclosures on pricing strategies.

Affordability & Pricing - Percentage change in: (1) list price and (2) net price of product with largest increase compared to previous reporting period (HC-BP-240b.3)

Similar to the previous metric, Bio Farma can develop a pricing transparency report that includes percentage changes in list prices and net prices over time.

Drug Safety - Number of fatalities associated with products (HC-BP-250.a.2)

Although there were no fatalities recorded, Bio Farma should keep reporting their record of fatalities associated with products. As in 2023 there were 0 fatalities, Bio Farma should report that fatalities which happened in 2023 were 0 fatalities. Also, they can strengthen Bio Farma's pharmacovigilance systems to track, analyze, and report adverse events and fatalities associated with its products.

Drug Safety - Total amount of product accepted for takeback, reuse, or disposal (HC-BP-250.a.4)

Bio Farma should adopt a structured *Product Takeback and Disposal Program* similar to industry leaders. Implement a reverse logistics framework to collect unused, expired, or defective products from customers and partners. Pfizer has implemented similar programs to ensure safe product disposal (Pfizer Environmental Impact Report, 2023). Answering this metric demand, track and report the total weight (in metric tonnes) of products accepted for takeback, reuse, and disposal is needed.

Drug Safety - Number of enforcement actions taken in response to violations of good manufacturing practices (GMP) or equivalent standards (HC-BP-250.a.5)

To improve transparency and ensure compliance, Bio Farma should implement rigorous GMP monitoring,

reporting, and enforcement systems. Best practices can be adopted from companies like Merck and GSK, because of several reasons below.

1. Enhanced Internal Audits
   Conduct regular GMP audits across production facilities and supply chain partners, documenting all non-compliance incidents and corrective actions. Merck publishes GMP enforcement data to demonstrate regulatory compliance (Merck Group Sustainability Report, 2023).
2. Third-Party Audits
   Partner with independent third-party auditors to evaluate GMP standards and provide impartial assessments of Bio Farma's facilities.
3. GMP Violation Reporting
   Develop a standardized reporting template that quantifies enforcement actions, including penalties, warnings, and remedial measures. This reporting aligns with the SASB requirements (HC-BP-250a.5).

By reporting quantifiable GMP enforcement actions and corrective measures, Bio Farma will align with industry leaders like Merck and GSK, improve operational transparency, and regain stakeholder confidence.

Counterfeit Drugs - Discussion of process for alerting customers and business partners to potential or known risks associated with counterfeit products (HC-BP-260a.2)

Bio Farma should implement a robust Counterfeit Product Risk Communication Protocol This can include setting up formalized procedures for early detection, notification, and collaboration with stakeholders. Leveraging their Whistleblowing System (WBS), Bio Farma should ensure timely updates to customers and partners through official platforms and communication channels, clearly describing counterfeit risks and preventive measures. The Merck direct description shows a good example of describing the issue, which highlights the positions of Merck to counterfeiting, which was decided on a case-by-case basis.

Counterfeit Drugs - Number of actions that led to raids, seizure, arrests, or filing of criminal charges related to counterfeit products (HC-BP-260a.3)

Bio Farma can publish the number of actions which led to raids, seizure, arrests, or filing criminal charges related to counterfeit products by year. If there are no actions of such issue, Bio Farma suggested to still report the 0 actions, which shows that Bio Farma has no counterfeit products to the readers particularly investors. The report is well embedded in their sustainability report.

Ethical Marketing - Total amount of monetary losses as a result of legal proceedings associated with false marketing claims (HC-BP-270a.1)

Similar solutions like point 10, Bio Farma can just disclose the total amount of monetary losses as the result of legal proceedings associated with false marketing claims. Transparency is the core of sustainability reports, but in this case, it is okay if Bio Farma decided not to report this metric specific amount, because this metric data may be confidentially prohibited, or better not to report it like GSK, Moderna, Pfizer, and Merck.

Ethical Marketing - Description of code of ethics governing promotion of off-label use of products (HC-BP-270a.2)

To strengthen their Code of Ethics for off-label promotion (HC-BP-270a.2), Bio Farma must revise and clarify their Code of Conduct. A specific section

dedicated to off-label product use should be developed, providing clear guidelines on ethical product promotion practices, regulatory boundaries, and consequences for non-compliance. Training programs for employees, especially those in sales and marketing, should be implemented to reinforce adherence to these policies.

Employee Recruitment, Development & Retention - (1) Voluntary and (2) involuntary turnover rate for: (a) executives/senior managers, (b) mid-level managers, (c) professionals, and (d) all others (HC-BP-330a.2)

For this specific metric, Bio Farma can add another section of turnover percentage in their sustainability report which includes the employee level; (a) executives/senior managers, (b) mid-level managers, (c) professionals, and (d) all others.

Supply Chain Management - Percentage of (1) firm's facilities and (2) Tier I suppliers' facilities participating in the Rx-360 International Pharmaceutical Supply Chain Consortium audit programme or equivalent third-party audit programmes for integrity of supply chain and ingredients (HC-BP-430a.1)

The company should prioritize the adoption of a formalized third-party audit program for its facilities and Tier I suppliers. While Bio Farma currently conducts internal audits, joining the Rx-360 International Pharmaceutical Supply Chain Consortium or adopting equivalent globally recognized third-party programs is essential to improve the transparency and credibility of their supply chain processes. This membership would ensure compliance with industry best practices for supply chain integrity, specifically for pharmaceuticals, while demonstrating a commitment to high standards of environmental, social, and ethical assessments. To further strengthen supply chain management, Bio Farma should collaborate with industry peers and organizations to share best practices and benchmark their processes. Participation in initiatives like Rx-360 will not only standardize their auditing practices but also foster collective progress in securing pharmaceutical supply chain integrity.

Benchmarking Analysis

Benchmarking analysis needed to compare leading pharmaceutical companies' SASB Biotechnology and Pharmaceutical metrics to find the best practices. The best practices are needed to improve the Bio Farma's current conditions to align with the SASB standard, which later the improvements can be constructed based on the best practices. The benchmark compares the SASB standard index of Biotechnology and Pharmaceutical, of leading companies in the lines of GSK, Pfizer, Moderna, and Merck. In deciding which is the best practices which Bio Farma can take example of, there are some considerations to take into account. The list below will explain all considerations, which combine those considerations to find the best practice in SASB index employment.

1. SASB Reporting Purpose

   SASB standards aim to deliver decision-useful information which carry sustainability-related risks and opportunities, by focusing on financially material, industry-specific metrics (SASB, 2022). Merck's approach of embedding detailed metric descriptions directly onto the SASB index can offer significant clarity and ease of access for investors. Contrary to GSK, Moderna, and

Pfizer, which linking to broader ESG reports, can dilute the effectiveness of disclosure because it requires navigating through those additional documentation. Merck's method can eliminate such barriers.

2. Investor Preference
   Khan, Serafeim, and Yoon (2016) said that companies that provide clear, decision-useful disclosures experience better financial performance and stronger relationships with stakeholders. This means that investors generally might prefer a straightforward and comprehensive data disclosure.
3. Contextual Depth
   While Merck's approach provides immediate clarity, the Pfizer, Moderna, and GSK practice method of linking the metrics description can gain more comprehensive contextualization. In this case, a hybrid approach might be appealing, which include a brief description and provide links for further details.
4. Comparability
   In competing with competitors, Bio Farma should ensure that their disclosures allow easy benchmarking against other companies for the readers. A direct description makes it easier for stakeholders to compare metrics.

By addressing these considerations, a hybrid method where each SASB metric fulfilled with needed descriptions and links for further detail is preferable since it can provide quick data disclosures and comprehensive contextualization from the detailed documents from the links.

CONCLUSION

The objective of this study is to find the gaps of PT Bio Farma disclosures to SASB Biotechnology and Pharmaceuticals standard. This case study is relevant in the light of integrating Bio Farma initiatives and efforts to an industry-based and decision-useful standard.

The integration of Bio Farma to SASB standard is using gap analysis which helps to identify deficiencies of current states relative to the standard metric. The metrics include various topics such as safety of clinical participants, access to medicines, affordability & pricing, drug safety, counterfeit drugs, ethical marketing, employee recruitment, development & retention, supply chain management, business ethics, and also activity metrics. The gap analysis shows that Bio Farma is insufficient in 16 metrics, which these holes are necessary to be improved. Each metric that insufficient, has different unique solutions that directly answer the issues A benchmark analysis also conducted to find the best practices in showing the SASB index inside the sustainability report, which shows that a hybrid method (concise and quick data disclosures and comprehensive contextualization from the detailed documents from the links) is more appealing.

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