Overview

ESG Issues for Biotechnology & Pharmaceuticals Companies

Amanda Rose and Ron Llewellyn, Fenwick & West

Bloomberg Law

ESG Issues for Biotechnology & Pharmaceuticals Companies

Editor's Note: In an effort to simplify the sustainability disclosure landscape, the International Financial Reporting Standards (IFRS) Foundation formed the International Sustainability Standards Board (ISSB) in November 2021. The IFRS is a not-for profit organization dedicated to the development of globally accepted accounting and sustainability disclosure standards. ISSB was tasked with creating a global baseline of sustainability-related disclosure standards.

The IFRS then consolidated Climate Disclosure Standards Board (CDSB) with the Value Reporting Foundation—which led SASB and the Integrated Reporting Framework—in August 2022. Since this consolidation, the ISSB has committed to building on the industry-based SASB Standards.

The Sustainability Accounting Standards Board (SASB) is an independent standards-setting organization that assists companies with the disclosure of financially material sustainability information to investors. See Overview – Sustainability Account Standards Board (SASB).

Contributed by Amanda Rose and Ron Llewellyn, Fenwick & West

The Sustainability Accounting Standards Board (SASB) has developed a sustainability accounting standard for the biotechnology and pharmaceuticals industries (the Standard), which consists of disclosure topics, accounting metrics, and activity metrics. In this overview of the Standard, we refer to the biotechnology and pharmaceuticals industries collectively as the "biopharma" industry and the companies within these industries as "biopharma" companies. Although this overview discusses the requirements to fully comply with the Standard, compliance with the Standard is voluntary, therefore, companies may choose the sections of the Standard for which they provide disclosure.

Industry

The biopharma industry develops, manufactures, and markets a range of medications. Demands for its products are driven by various factors, including population demographics, insurance coverage, disease profiles, and the economic environment. Research and development (R&D), risk of product failure, regulatory approval, and drug pricing can affect the performance of companies in the biopharma industry.

The Standard provides a means whereby investors can assess how these, and other pertinent factors, may affect the ability of biopharma companies to create long-term value.

Topics & Accounting Metrics

The Standard identifies the disclosure topics and related accounting metrics below as the most relevant for biopharma companies.

Safety of Clinical Trial Participants

The Standard provides for biopharma companies to disclose several matters related to conducting clinical trials such as:

- Oversight of clinical research organizations (CROs), which are scientific organizations to which companies transfer some of their tasks and obligations for clinical trials.
- Management processes for CROs broken down by world region.
- Processes for obtaining informed consent for participants in clinical trials.
- List of clinical trials, including those conducted by CROs or other third parties for a company's benefit, that were terminated for failure to follow good clinical practice (GCP) standards.
- List of all terminated clinical trials

In addition, the Standard calls for biopharma companies to disclose the number of US Federal Drug Administration (FDA) inspections related to clinical trial management and pharmacovigilance that resulted in Voluntary Action Indicated (VAI) and Official Action Indicated (OAI). VAI is an FDA classification that indicates objectional conditions were found but the FDA is not prepared to take or recommend regulatory action. OAI is an FDA classification that indicates objectional conditions were found and regulatory action should be recommended.

Also, the Standard requires disclosure of the total amount of monetary losses from legal proceedings associated with clinical trials in developing countries during the reporting period. Companies should describe any corrective actions taken in response to such legal proceedings, including changes to operations, management, processes, products, business partners, training, or technology.

Access to Medicines

The Standard also seeks information regarding a biopharma company's policies and practices to ensure that people around the world, including those in developing countries, have access to its products. Accordingly, the Standard calls for companies to disclose their 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 during the reporting period.

The Access to Medicine Foundation, which sponsors the Access to Medicine Index, considers the priority issues and diseases in priority countries to be those with the highest Disability Adjusted Life Years (DALY) according to World Health Organization (WHO) data. This disclosure shall also include information regarding products authorized for sale during the reporting period by the WHO. A company may disclose the number of products for each therapeutic area defined by the WHO.

Affordability & Pricing

The Standard also provides for biopharma companies to disclose accounting metrics related to drug affordability. In particular, a company should disclose its:

- Number of Abbreviated New Drug Application (ANDA) legal settlements related to patents under the Drug Price Competition and Patent Term Restoration Act (the Hatch-Waxman Act) that involved payments to generic drug manufacturers and/or provisions to delay bringing a generic drug to market.
- Average list price and average net price increase across its US product portfolios over the previous year. The net price represents the list price—defined as the average wholesale acquisition cost—minus rebates, discounts, and returns.
- Percentage change in list price and net price of its product with the largest increase compared to the previous year.

For more general information on billing, see In Focus: Surprise & Balance Billing.

Drug Safety

Issues involving the adverse effects of medications and related recalls can negatively affect biopharma companies. Accordingly, the Standard includes five accounting methods related to drug safety. Under the accounting metrics a company must disclose:

- All drugs and therapeutic biological products listed on the FDA's MedWatch Safety Alerts for Human Medical Products or the FDA Adverse Event Reporting System (FAERS) database.
- The number of fatalities associated with the drugs or biologic products that it manufactures as reported through FAERS.
- The number of recalls issued and the total number of units recalled both in the US and internationally, whether voluntarily or by the request of the FDA or an equivalent statutory authority.
- The amount in metric tons of unused products accepted for take-back, reuse or disposal.

- The number and type of FDA enforcement actions related to violations of Current Good Manufacturing Practices (CGMP) at its facilities.

When disclosing the number of recalls, companies must provide the percentage of recalls that are voluntary, FDA-requested, and FDA-mandated. For FDA-mandated recalls, companies may disclose the product's FDA classification—i.e., Class I, II or III. For each recalled product companies may also report associated revenues from the 12 months that preceded the recall. Finally, companies should specify notable recalls that have affected a significant number of units or caused serious injuries and should provide relevant details and outcomes regarding those recalls including the cause, total number of units recalled, remedial costs, corrective actions, and whether they were voluntary.

Where a company is involved in a take-back initiative that it co-funds, it must prorate the amount of product that is accepted for take-back by its percentage contribution to fund the initiative. A company must also discuss end-of-life management of its products to prevent abuse, illegal sales, or release into the environment.

If a company has been subject to cGMP enforcement action, it must disclose the nature and context of the enforcement action as well as any corrective action taken to remedy each violation, such as changes in operations, management, processes, products, business partners, training, or technology.

Counterfeit Drugs

Counterfeit drugs pose a danger to patients and consumers. Failure to address them may negatively impact a biopharma company's revenue. The Standard includes three accounting metrics for biopharma companies to address their approach towards counterfeit drugs:

- Description of methods and technologies used to maintain the traceability of products throughout the supply chain and prevent counterfeiting.
- Discussion of the process for alerting customers, including patients and physicians, and business partners—e.g., suppliers, wholesalers, retailers, and hospitals—of potential or known risks from counterfeit products.
- Disclosure of the number of actions that led to raids, seizure, arrests and/or filing of criminal charges related to counterfeit drugs.

A company must disclose information regarding the type and sophistication of the technology that it uses to prevent the counterfeiting of its products, including the use of barcode technology and radio frequency identification (RFID) tagging. A company must also disclose the actions that it took to alert law enforcement or regulatory authorities, such as the FDA, of counterfeit activities and the outcomes.

For general information on health fraud, see Practical Guidance: Fraud & Abuse.

Ethical Marketing

To demonstrate efforts taken to ensure that its products are marketed responsibly and to prevent misuse, the Standard requires a biopharma company to disclose:

- The total amount of monetary losses in connection with legal proceedings involving claims of false marketing.
- Code of ethics provisions relating to the promotion of off-label uses for its products.

In its disclosure, a company must describe the nature and context of any monetary loss resulting from the legal proceeding and any corrective measures that it has undertaken in response. A code of ethics shall include any corporate policy, code of conduct, guideline, or contractual term that is similar in intent to a code of ethics. A company must also describe mechanisms in place to ensure compliance with its code of ethics, including disciplinary action, training, internal audits, and regulatory review committees.

Employee Recruitment, Development & Retention

Given the importance of attracting and retaining employees to sustain operations and provide for growth, the Standard provides for the disclosure of metrics concerning the recruitment and retention efforts for scientists and R&D personnel and turnover rates for executives/senior managers, mid-level managers, professionals, and all other employees. Retention and recruitment programs may include mentorship and career development programs, leadership training and incentives.

In disclosing its turnover rate, which is calculated by dividing the number of employee terminations by the average number of employees each month, a company must provide data regarding monthly voluntary and involuntary terminations.

Supply Chain Management

The Standard requires a company to disclose the percentage of its facilities and its Tier I supplier's facilities that participate in the Rx-360 International Pharmaceutical Supply Chain Consortium (Rx-360) audit program or an equivalent third-party audit program. Rx-360 is a nonprofit international consortium of life science and medical device thought leaders that addresses pharmaceutical and medical device supply chain security issues. Information regarding its audit programs may be found on its website.

For more general information on developing sustainable supply chain policies, see Checklist- Establishing a Sustainable Supply Chain Policy.

Business Ethics

Maintaining responsible business practices and ensuring compliance with applicable laws is important for all companies, especially biopharma companies. Accordingly, the Standard provides that companies must disclose:

- Total monetary losses resulting from legal proceedings related to corruption and bribery.
- Their codes of ethics governing their interactions with healthcare professionals.

The first accounting metric related to monetary losses, encompasses a broad range of legal proceedings including any adjudication involving the company, such as those before a court, arbitrator, or regulator. Disclosures should be provided for all monetary liabilities, including settlement amounts. If a company has been subject to such monetary losses, it must disclose the nature and context of each loss and any corrective actions that it has taken as a result.

To satisfy the second metric, a company must disclose how its code of ethics—or an equivalent policy—relates to its interactions with health care professionals. Health care professionals include physicians, dentists, pharmacists, nurses, and indirect providers of the company's products such as purchasing agents, practice managers and group purchasing organizations.

The description of the code of ethics should include topics covered, e.g., food and entertainment, training, and education; its scope, e.g., whether there are any limitations to the employees to which it relates; and enforcement. If a company has adopted a second- or third-party code of ethics—e.g., PhRMA's Code on Interactions with Health Care Professionals—it may just reference it without providing a description.

Activity Metrics

In addition, the Standard provides for activity metrics regarding the number of patients treated and the number of drugs in the company's portfolio and R&D phase.