Checklist

ESG Disclosures for Biotechnology & Pharmaceuticals Companies (Annotated)

Amanda Rose and Ron Llewellyn, Fenwick & West

Bloomberg Law

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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). The issues outlined in this document are outlined by SASB across six industries: biotechnology and pharmaceuticals, drug retailers, health care delivery, health care distributors, managed care, and medical equipment and supplies.

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. Although this checklist discusses the requirements to fully comply with the Standard, compliance is voluntary and companies may choose the sections of the Standard for which they provide disclosure. For an overview of issues in this industry, see Overview – ESG Issues for Biotechnology & Pharmaceuticals Companies.

Contributed by Amanda Rose and Ron Llewellyn, Fenwick & West

Safety of Clinical Trial Participants

☐ Describe processes and procedures for tracking the number of inspections, VAIs and OAIs both for a company's own clinical trials and those conducted by a CRO on its behalf.

> **Practice Tip**: A company may search the FDA's Clinical Investigator Inspection List (CLIIL) by investigator or location via the FDA's website to see its or its CRO's VAIs and OAIs. The results are included in the classification column.

☐ Describe processes for overseeing and managing clinical research organizations (CROs) and related clinical trials, including regular audits or inspections and enforcement mechanisms.

> **Practice Tip**: Investors are likely to analyze such processes and procedures for benchmarking against other biopharma companies. Therefore, consider analyzing the practices of other biopharma companies when developing or modifying existing policies and procedures for CROs. Such policies and procedures should include tracking the nature and terms of any monetary incentives provided to CROs, excluding reimbursements for meals, travel, or lodging.

☐ Ensure policy for obtaining informed consent from clinical trial participants provides enough information to fully allow the participant to make an informed decision, facilitates an understanding of such information, and promotes the voluntary nature of the clinical trial.

Access to Medicines

☐ Document and disclose actions and initiatives to promote access to medicines for priority diseases in priority countries as defined by the Access to Medicine Index.

> **Practice Tip**: The Access to Medicine Index can be found on the Access to Medicine Foundation's website. 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. A full list is included in the Methodology for the index which can also be found on the foundation's website.

☐ Create a list of the company's products on the WHO List of Prequalified Medicinal Products.

> **Practice Tip**: The List of Prequalified Medicinal Products can be found on the WHO's website. Use the product's International Nonproprietary Name (INN), including the brand name in parentheses as applicable, when searching for a product on the website.

Affordability & Pricing

☐ Track and disclose the number of settlements of Abbreviated New Drug Application (ANDA) litigation that resulted in payments and/or provisions to delay bringing an authorized generic product to market for a defined time period.

> **Practice Tip**: Payments include implicit compensation such as reduced royalty payment for delayed market entry or an agreement by another company not to introduce its own authorized generic product during the 180-day "first filer" period under the Hatch-Waxman Act.

☐ Annually compile data regarding: i) the average list price increase and average net price increase across the company's US product portfolio and ii) the product with the largest increase in list price and net price compared to the previous year.

> **Practice Tip**: The Standard defines the list price as the average wholesale acquisition cost (WAC) and the net price as the WAC minus rebates, discounts and returns.

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

Drug Safety

☐ Compile a list of and disclose all products on the FDA's MedWatch Safety Alerts for Human Medical Products and the FDA Adverse Event Reporting system (FAERS) database.

☐ Compile a list of and disclose the number of fatalities associated with the company's drugs and biologic products.

> **Practice Tip**: Access the MedWatch Safety Alerts for Human Medical Products and FAERS database on the FDA's website. The company may search the database under the "biologics" or "drugs" product type.

☐ Compile a list of and disclose the number of drug recalls for products manufactured by the company or its subsidiaries. Such list should also include the total number of units involved and the percentage that was: i) voluntary; ii) FDA-requested and iii) FDA-mandated. The company should also identify and discuss any notable recalls.

> **Practice Tip**: Review weekly enforcement reports published by the FDA on its website, which provides recall information to confirm the accuracy of the company's list. Recalls are listed by product type, product description, company name, recall reason, and date.

☐ Disclose the amount of unused product that is accepted through take-back initiatives and systemic efforts to manage the end-of-life of the company's products, including efforts to prevent back-market sales, abuse, and release into the environment.

> **Practice Tip**: If the company co-funds a take-back initiative, it may pro-rate the amount of product accepted for take-back by its percentage contribution to the initiative.

☐ Track and disclose the number of FDA enforcement actions taken in response to Current Good Manufacturing Policies (cGMP) violations at the company's facilities.

Counterfeit Drugs

☐ Analyze and describe the company's processes to prevent counterfeiting of its products, including how customers and business partners are alerted about risks.

☐ Track and disclose the number of instances in which the company alerted or assisted regulatory authorities, such as the FDA, or law enforcement agencies with matters that led to raids, arrests, seizures, or the filing of charges related to counterfeit products.

☐ Document for disclosure all actions taken by the company and the outcome of each instance of actual or suspected counterfeiting.

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

Ethical Marketing

☐ Calculate and disclose the total amount of monetary losses from legal proceedings involving false marketing claims.

☐ Identify or draft and describe provisions in the company's code of ethics that relate to ethical marketing and off-label promotion.

> **Practice Tip**: A company should ensure that such provisions define "off-label promotion" and address topics such as disciplinary actions, training, internal audits, and regulatory review committees. A "code of ethics" can be a corporate policy, code of conduct, guideline or contractual term that is similar in intent to a code of ethics. A company should periodically benchmark its code of ethics' provisions related to ethical marketing and off-label promotion with those of other biopharma companies to ensure that its provisions reflect market practice.

Employee Recruitment, Development & Retention

☐ Describe the company's strategy to recruit and retain scientists and other R&D personnel, including mentorship and career development programs, leadership training, and incentives.

> **Practice Tip**: a company should consider discussing the implementation, participation rates and effectiveness of its strategy in its disclosure.

☐ Track and disclose the monthly voluntary and involuntary turnover rates for i) executives/senior managers, ii) mid-level managers, iii) professionals, and iv) all other employees.

Supply Chain Management

☐ Calculate and disclose the percentage of the company's facilities and Tier I suppliers' facilities that participate in the Rx-360 International Pharmaceutical Supply Chain Consortium audit program.

> **Practice Tip**: The company may limit its disclosure to suppliers that account for at least 90% of its supplier spending.

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

Business Ethics

- ☐ Calculate and disclose the total amount of monetary losses related to legal proceedings connected to corruption and bribery.
- ☐ Describe the nature of such legal proceedings, including any corrective actions that the company has implemented because of the legal proceedings.
- ☐ Describe the provisions of the company's code of ethics that govern its interactions with health care professionals including mechanisms for compliance.

Activity Metrics

- ☐ Track and disclose the number of patients treated.
- ☐ Track and disclose the number of drugs in: i) the company's portfolio and ii) the R&D phase.