

Checklist: 10 ESG Principles for Biotech Companies

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Environmental, social and governance topics are a priority for companies across various industries, particularly for biotech companies. Biotech’s focus on innovation and improving human health presents unique ESG opportunities and challenges. These must be properly managed to build a robust ESG program that creates long-term value and meets investors’ expectations.

Here are 10 principles for biotech companies to consider when designing or bolstering an ESG program:

- 1. The “S” is paramount for biotech.** While “E” (environmental) and “G” (governance) are considered by some to be the most important pillars of ESG, social issues are paramount for biotech. Biotech’s mission centers on human health and well-being. A broad array of stakeholders, including patients, health care providers, investors and employees, are impacted by company action. ESG reporting and other disclosures from biotech companies should reflect their social purpose and how they take the social impacts on their stakeholders into account.

Biotech companies also face significant social risks given the role of their products and services. From the safety of patients in the clinical trial process to drug safety and affordability, biotech companies’ decisions risk negatively impacting lives and destroying brand value. As a core part of their ESG programs, biotech companies should have governance mechanisms in place for managing social risks to protect long-term value.

- 2. Share the benefits of your products.** ESG is not just about risk — it is also about opportunity. Biotech companies have a mission to help improve human health. This mission creates ESG opportunities for biotech companies that relate to both their products as well as business processes. ESG for biotech includes seizing opportunities to improve people’s standard of living. Biotech companies can share the benefits of their products through leading ESG frameworks such as the [UN Sustainable Development Goals](#). Contributions to the third [SDG](#), “Good Health and Well-Being,” should be considered by any biotech company that is preparing an ESG report.

Biotech companies can focus on new opportunities for advancing human health through a responsible innovation framework that takes into consideration broader social impacts of new products. There can be positive effects on shareholder value when new products lead to increased market share or brand value. Biotech companies should establish and disclose their approach to responsible innovation in their ESG reports.

- 3. Patient safety is a core ESG topic.** ESG is leading to more disclosure and scrutiny of patient safety. Biotech companies should be ready to describe their approach to patient safety in ESG reporting and other disclosures. Patient safety can be managed through robust clinical studies, proper management systems in production and surveillance of products on the market. Biotech companies should include efforts across these areas in their ESG disclosures.

There are also specific ESG metrics on patient safety that biotech companies should also be ready to disclose. Leading ESG frameworks, including the [Sustainability Accounting Standards Board](#), require biotech companies to disclose the number of severe product recalls and Food and Drug Administration enforcement actions on an annual basis. Sophisticated ESG investors use this information for their valuation models and voting decisions, and biotech companies should ensure that patient safety data is internally reviewed and validated before disclosure.

- 4. Put access and affordability on the agenda.** Access and affordability are priority ESG topics for biotech companies. Affordability is an increasing challenge to companies that have historically relied on raising product prices to protect profits. Such business models may be seen as a risk to ESG-aligned investors. For instance, the SASB standards highlight the legislative emphasis on health care cost containment in the U.S. as a potential ESG risk for companies in the medical equipment and supplies sector. Biotech companies should develop an approach for managing these challenges, and establish a framework to balance decisions that weigh short-term profits against broader expectations (including social benefits) for access and affordability.

Along with a description of their approach to access and affordability, biotech companies should be ready to include key metrics on affordability in their ESG disclosures. The SASB standards require biotech companies to disclose the ratio of average price increases against inflation. They also require a

description of how pricing information is communicated to customers and patients.

- 5. Success requires proper governance.** ESG is a board and executive-level issue. Biotech companies should be ready to disclose their approach to ESG oversight and management. At a minimum, biotech companies should establish a board-level committee with explicit oversight of ESG matters, including patient safety. Companies should ensure that the board members serving on this committee possess the necessary skills and experience, including medical expertise. This committee should review company performance on ESG ahead of public disclosure.

Companies should also secure buy-in and alignment of their business strategies and implementation through a management committee. This committee should be made up of representatives from across the company, including representatives from product development, patient safety, marketing, regulatory affairs and legal. Company leadership needs to determine priority ESG topics, and should consider incorporating ESG goals and metrics into performance targets to ensure accountability and drive a successful ESG program. A strong tone from the top is necessary to develop an effective ESG program.

- 6. Business ethics is a top governance priority.** ESG is driving increased disclosure on business ethics. Biotech companies should formulate policies on industry-specific ethical issues, including ethical interactions with health care professionals, responsible marketing and responsible product testing practices. Companies should be ready to disclose any such policies that are in place. Biotech companies need to have a proactive approach to business ethics and they should ensure robust compliance programs are a part of the ESG agenda.

Product testing practices in pharmaceutical/life science/biotech sectors have been an ethical hot button for many years. This relates to animal testing as well as clinical studies on humans. Companies should be transparent in discussing the ethical considerations in product testing protocols balanced by the ultimate social benefit anticipated from a successful product once launched.

When formulating a policy on interactions with health care professionals, biotech companies should evaluate the guidance of industry associations. Examples include [PhRMA](#) for pharmaceutical and biotechnology companies and [AdvaMed](#) for medical technology companies. Companies should also develop an ethical marketing approach, and be prepared to disclose their marketing code of ethics and any legal and regulatory fines from marketing activities.

- 7. Cybersecurity is a growing ESG issue.** Biotech companies should view cybersecurity as a high-priority ESG topic. Data breaches at health care organizations impacted [more than 1 million people in each month of 2020](#), and cybersecurity attacks against health care organizations reached an [all-time high in 2021](#). Cybersecurity is a serious product safety concern for medical devices. Cyberattacks can impact functionality and threaten patient health. A recent high-profile case from 2021 is the Log4Shell vulnerability, which affected [more than 90%](#) of all enterprise cloud environments. The FDA issued an [alert](#) in December 2021 indicating that the vulnerability threatened medical devices as well as supporting systems that remotely logged security and performance information.

An aspect of cybersecurity that is frequently overlooked are process control systems in the manufacturing lines. Biotech uses an array of raw material that pose significant chemical, fire and biohazard risks when used in an uncontrolled manner. Breaches of process control systems can result in fires, explosions, chemical or process venting, bypassing of radioactive material monitoring/safety equipment and disabling pollution control equipment — all of which pose meaningful health and safety risks to employees, the community and emergency responders.

Biotech companies should be ready to disclose their approach to cybersecurity in their ESG reports. These disclosures should include the company's plans for proactively monitoring and addressing new cybersecurity vulnerabilities, and provide metrics on the number of patients and customers affected by data breaches or cyberattacks. With regard to disclosing information about process control systems, care should be taken to balance the disclosures with confidential or proprietary information, as well as information considered sensitive under Department of Homeland Security Chemical Facilities Anti-Terrorism Standards regulation that applies to facilities possessing any DHS-

regulated chemicals of interest at or above specific quantities and concentrations.

The FDA provides [guidance](#) to medical technology manufacturers to help them design and maintain more cyber-secure products. Biotech companies should consider implementing such guidance with respect to their operations.

- 8. Don't forget the "E" in ESG.** While social issues are the top priority, biotech companies still need to meet stakeholder expectations on environmental topics. Environmental topics under the ESG umbrella cover a wide range of issues, including climate change, water use, pollution and waste management. When communicating their performance on environmental sustainability, biotech companies should refer to external [reporting guidance](#), collect and disclose performance data, and publish targets on key environmental initiatives.

One of the most important environmental issues for the biotech sector is medical waste. Health care waste may be infectious, chemical or radioactive. This presents both human health hazards and environmental risks. According to the World Health Organization, [15% of health care waste is hazardous](#). There can be significant waste streams that come from single-use and disposable biotech products — and different sovereign regulatory mandates, which creates problems itself. Biotech companies may face questions about why a waste is managed differently in different countries/jurisdictions. They should develop a strategy to manage and improve performance on health care waste over time. Companies should consider implementing circularity measures across the product lifecycle, from product development to patient disposal.

- 9. Climate change is a priority for everyone.** Climate change is an issue for companies across the board. Institutional investors have broad expectations for companies to disclose their greenhouse gas emissions and meet net-zero targets. The health care sector's greenhouse gas emissions comprise [4.4% of global emissions, with emissions located across the industry's value chain](#). To operate more sustainably, biotech companies can set emission reduction targets through the [Science Based Targets initiative](#). Publicly listed biotech companies should also carefully track the SEC's proposed rule on climate disclosures and take steps now to prepare for additional climate disclosure

requirements. Companies subject to EU regulation should also stay updated on the developing IFRS [International Sustainability Standards Board](#) and [EFRAG](#) standards for ESG and climate disclosures, which may contain inconsistencies across them.

- 10. Stay on top of new and emerging industry-specific ESG issues.** ESG includes a wide and changing set of issues. Stakeholders may have divergent views on what ESG topics are most important, and new ESG issues may become increasingly important over time. Biotech companies can better understand the shifting landscape of ESG by leveraging industry organizations and initiatives, such as the [Biopharma Sustainability Roundtable](#), [Access to Medicine Foundation](#), the World Bank's [Ethical Principles in Health Care](#) and [Health Care Without Harm](#). These organizations and initiatives are good resources for companies that want to advance their ESG programs.

As part of their ESG program, biotech companies should regularly assess established and emerging ESG topics. Companies should conduct regular ESG Priority Assessments to align with leading ESG standards, including SASB and the Global Reporting Initiative. On an annual or biannual basis, biotech companies should review which issues matter most to the company and external stakeholders, including patients, stockholders and customers.