



BIOTECHNOLOGY

Research Brief

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Research Brief

SASB's industry brief provides a summary of the material sustainability issues that are likely to impact shareholder value. The issues identified within are industry specific, and reflect how the associated companies rely on environmental, social, and human capital. Further, the brief identifies material sustainability issues that pertain to business model and innovation, and governance. SASB adheres to the U.S. Supreme Court definition of materiality, defined as "presenting a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." To identify material sustainability issues, SASB's research team examines three types of evidence; evidence of interest, evidence of financial impact, and forward looking impact. The research reflected within this document was conducted by SASB and an initial version of the document served as an input for the Industry Working Groups to evaluate the materiality of industry issues and potential accounting metrics. The industry brief is not the disclosure standard, but rather is intended to provide background context and evidence for the material sustainability issues that SASB identified for the given industry. SASB takes sole responsibility for errors and omissions.

Related Documents

- [Health Care Sustainability Accounting Standards](#)
- [Industry Working Group Participants](#)
- [SASB Conceptual Framework](#)
- [Example of Integrated Disclosure in Form 10-K](#)

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MATERIAL SUSTAINABILITY ISSUES

Environmental Capital

- Energy and Waste Efficiency

Social Capital

- Access to Medicines
- Safety of Clinical Trial Participants
- Ethical Marketing
- Counterfeit Drugs
- Drug Safety and Side Effects
- Affordability and Fair Pricing

Human Capital

- Employee Recruitment, Development and Retention
- Employee Health and Safety

Business Model and Innovation

Governance

- Corruption and Bribery
- Manufacturing and Supply Chain Quality Management

INDUSTRY SUMMARY

Biotechnology companies develop novel products that treat previously unmet medical needs through the technological application of molecular and cellular systems. The industry is driven by research and development, and is characterized by a high risk of product failure. Biotechnology firms are dependent on a skilled workforce and are closely regulated.¹

Increasing life expectancy and expanded health insurance coverage under the Patient Protection and Affordable Care Act are expected to drive growth in the biotechnology industry. Emerging markets also present significant opportunities. Pricing pressures from reimbursement agencies and the need for research and development funding could result in additional mergers and acquisitions. Approval rates by regulatory agencies will also impact growth in the biotechnology industry.

The biotechnology industry provides an essential public good in providing treatments for a range of medical conditions. However, companies in this industry must respond to changes in both the legislative and regulatory environment. Recent trends suggest a further

¹ A list of the top five companies by revenue appears in Appendix I

alignment between the interests of society and those of long-term investors. These trends will also amplify how non-financial forms of capital contribute to market value. More specifically, the management of environmental, social, and human capital will increasingly affect traditional valuation by impacting revenue, cash flow, and costs of capital. The ability of companies to manage these issues while also addressing the associated risks and opportunities through business models, innovation, and governance will be strong indicators of management quality and long-term value.

To ensure that shareholders are able to evaluate performance in these areas, biotechnology companies should report on the sustainability issues that will have a material impact in the near and long term. Enhanced reporting will provide stakeholders with a more holistic (and comparable) view of performance that includes both positive and negative externalities, as well as the non-financial forms of capital that biotechnology companies rely on to create long-term value.

The sustainability issues that will drive competitiveness within the biotechnology industry include:

- Improving resource efficiency in manufacturing processes
- Facilitating access to medicines by underserved populations
- Focusing on clinical trial and drug safety and minimization of side effects
- Marketing products in an ethical manner
- Working to reduce the threat to business and consumer safety posed by counterfeit drugs
- Improving affordability of treatments
- Managing human capital and ensuring employee health and safety
- Complying with U.S. and international regulations relating to corruption and bribery
- Managing manufacturing and supply chains to ensure excellence

The extent to which these sustainability issues impact value will become increasingly clear as the legislative and regulatory environment continues to evolve, and emphasize increased access, reduced costs, and safety.

LEGISLATIVE AND REGULATORY TRENDS IN THE BIOTECHNOLOGY SECTOR

Although the legislative and regulatory environment that governs the biotechnology sector continues to evolve, recent and future developments have the potential to impact shareholder value and further demonstrate the materiality of sustainability performance. The following section provides a brief summary of key trends that are likely to impact value in the industry and to further amplify the importance of sustainability issues.

The Patient Protection and Affordable Care Act (PPACA) will increase the number of insured by an estimated 26 million.^{1,2} The law will subsequently expand demand for biotechnology products through increased rates of insurance coverage, but will also present certain challenges. These risks are associated with requirements for discounts and rebates for Medicare participants, which could have negative impacts on profitability. Current estimates suggest that the biotechnology and pharmaceutical industries will pay \$80 billion in fees and rebates collectively to help fund the plan over ten years.ⁱⁱⁱ

In addition, the PPACA includes provisions that allow the U.S. Food and Drug Administration to approve biosimilar versions of previously approved biotechnology drugs. The path to approval for biosimilars is yet to be defined,

but is expected to reduce the profitability of biologics through increased competition. Conversely, the provision could provide opportunities for companies to engage in the development of biosimilars.

The American Recovery and Reinvestment Act of 2009 included provisions for \$1.1 billion dollars in funding for the advancement of comparative effectiveness research (CER). The framework is intended to give health care providers the necessary information to make value-based decisions. CER will encourage biotechnology companies to further substantiate the effectiveness of their products during clinical trials, and could result in increased emphasis on biosimilars or alternative therapies.

SUSTAINABILITY RISKS AND OPPORTUNITIES

Recent legislation in the U.S. indicates an effort to increase health insurance coverage, while reducing health care costs, and alleviating some barriers to entry for new products. Companies will therefore not be able to maximize financial capital unless they address material sustainability issues as well. Specifically, firms that are able to navigate new regulations while addressing all forms of capital and limiting negative externalities will be better positioned to protect shareholder value in the long term.

² Estimates range between 26 and 30 million for the number of people that will become insured under the PPACA.

The following section provides a brief description of each sustainability issue that is likely to have material implications for the biotechnology industry. The description includes evidence of materiality and a link to valuation. The issues are divided into five categories: Environmental Capital, Social Capital, Human Capital, Business Model and Innovation, and Governance. Tables outlining the type of evidence of materiality and the recommended disclosure framework appear in Appendices II and III, respectively. An analysis of the current state of reporting on material sustainability issues in the biotechnology industry appears in Appendix IV.

ENVIRONMENTAL CAPITAL

Biotechnology companies engage in research and manufacturing processes that rely heavily on environmental capital. Firms in this industry depend on the ability to utilize purchased resources (i.e., energy, water, and material inputs). In addition, companies generate negative externalities through air emissions and water pollution. As resources become limited, and legislation seeks to address these externalities, investors must understand how individual companies within this industry manage these risks and adhere to societal expectations.

Energy and Waste Efficiency

The manufacturing of biotechnology products requires the use of energy, water, and material inputs, in addition to the creation of waste. As concerns over climate change and dwindling natural resources continue to impact pricing, biotechnology companies will be exposed to fluctuations in costs of these key inputs. Firms that are able to improve manufacturing efficiencies and limit dependence on finite resources are likely to enhance shareholder value.

Evidence

Amgen reports that its energy efficiency measures have resulted in annual savings of \$11 million. Through the elimination of acid from cleaning cycles in their Research Triangle Park, Biogen Idec saved 3.4 million gallons of water and \$2.3 million in costs from chemical reductions between 2009 and 2011.

Value Impact and Timing

Biotechnology companies that are able to manage their energy, water, and waste efficiency will reduce current and future operating costs and hedge against likely increases in resource pricing.

SOCIAL CAPITAL

Biotechnology companies require strong intellectual property protection to ensure returns on research and development investments. These protections and the associated regulatory procedures create a significant link between the industry and social capital, and an expectation that medications are safe, accessible, and affordable. Biotechnology companies also face a risk to profits, reputation, and consumer safety associated with the growing global trade in counterfeit drugs.

Access to Medicines

Biotechnology companies play an important role in providing access to the industry's products around the world. Firms can develop pricing frameworks that account for differing levels of economic development and health care needs across various countries. Further, the industry can target priority diseases in developing countries. A strategic approach to access to medicines can yield opportunities for growth, innovation, and unique partnerships, which can enhance shareholder value.

Evidence

Gilead Sciences has developed strategic partnerships with distributors, manufacturers, and the Medicines Patent Pool to increase the accessibility of its branded drugs and generic equivalents. The company reports that 2.7

million patients in developing nations are currently receiving Gilead's HIV therapies at reduced costs. In addition, companies continue to report that emerging markets represent a significant growth opportunity.

Value Impact and Timing

Companies that are able to develop innovative operating models that provide lower price points and increase access to medicines will have the opportunity to capitalize on new revenue streams. In addition, although the research, development, and release of new products targeting priority diseases in developing nations take multiple years, success in this area can also present positive impacts on profits and assets.

Safety of Clinical Trial Participants

Clinical trials are an essential component of the approval process for biotechnology products. The safety of clinical trial participants reflects a company's ability to successfully bring a product to market. Oversight of these trials is of increasing importance as the number of clinical trials conducted by third party contract research organizations in emerging countries continues to rise. Biotechnology companies that effectively manage clinical trials will be positioned to enhance shareholder value through the revenue associated with new products.

Evidence

A 2010 report by the Department of Health and Human Services indicates that in 2008, 80 percent of approved applications for drugs and biologics contained data from foreign clinical trials. However, the FDA inspected less than one percent of foreign sites.ⁱⁱⁱ

The death of a patient in a Bristol-Meyers Squibb clinical trial for a hepatitis C drug resulted in reduced analyst sales estimates of between \$34 and \$800 million for 2016. The company experienced a subsequent 10 percent drop in stock value.^{iv}

Value Impact and Timing

Companies that effectively manage the safety of their clinical trial participants have an increased likelihood of achieving regulatory approval, and actualizing the associated revenue. Further, the failure to conduct safe and effective clinical trials could result in liabilities and an increased cost of capital.

Ethical Marketing

Biotechnology companies face challenges associated with the marketing of specific products. Consumer-directed advertisements for prescription drugs in the U.S. provide opportunities for increasing market share. However, challenges also arise from the potential for marketing off-label uses. Corporate disclosure of legal and regulatory fines and the codes of ethics that govern interactions with health professionals will allow shareholders to monitor performance in this area.

Evidence

In recent years, significant fines have been levied against companies for illegal marketing of products under the False Claims Act. In 2012, GlaxoSmithKline paid \$3 billion for marketing two of its products for off-label use, and for making false statements about another drug.^v Abbot Laboratories paid \$1.5 billion for marketing Depakote for off-label use, which amounts to approximately 17.5 percent of estimated profits for 2012.^{vi}

Value Impact and Timing

Recent examples of fines associated with illegal marketing demonstrate the potential for such practices to lead to significant fines which can impact profits and generate liabilities.

Counterfeit Drugs

The World Health Organization estimates that the global market for counterfeit drugs has reached \$431 billion, representing one percent of the U.S.'s supply, and ten to 15 percent of the world's pharmaceuticals market.^{vii,viii} This issue presents a significant health and safety risk to consumers with an estimated 100,000 annual deaths attributed to standard or counterfeit drugs worldwide.^{ix} Biotechnology companies subsequently face material risks associated with the potential loss of public confidence and reduced revenue.

Evidence

In 2012, fake Avastin was distributed to pharmacies and doctors in the U.S. Avastin, a cancer medication produced by Roche Holdings' Genentech division, typically sells for \$2,400 per 400-milligram vial, and produced \$2.5 billion in sales in 2011. According to the Pharmaceutical Security Institute, cancer drugs currently rank eighth among the top ten types of drugs being counterfeited.^x This indicates a shift in which counterfeiters are beginning to target more expensive drugs, presenting a significant threat to industry revenues in addition to consumer welfare.

Amgen reports that “public loss of confidence in the integrity of biologics and/or pharmaceutical products as a result of counterfeiting or theft could have a material adverse effect on our product sales, business and results of operations.”

Value Impact and Timing

An influx of counterfeit drugs in the U.S. and abroad will impact profits, and could diminish consumer confidence in the industry. As the market for biotechnology products continues to grow, along with the industry's reliance on a global supply chain, the severity of this issue is likely to increase.

Drug Safety and Side Effects

Information on product safety and side effects can surface after controlled clinical trials and approval. Subsequently, companies are exposed to the financial implications of recalls and other adverse events. Biotechnology firms that work to limit safety issues will be better positioned to protect shareholder value. In addition, concern over the abuse or resale of certain medications has led to mandated take-back programs. Firms that are able to successfully engage in these programs will likely limit future liabilities.

Evidence

In 2010, product recalls and plant slowdowns related to safety concerns cost Johnson & Johnson \$900 million.^{xi,xii} Estimates indicate that the recall of four Novartis products in 2011 resulted in lost revenue of between \$560 and \$750 million, or 1.4 percent to 1.8 percent of gross profit.^{xiii}

In November 2012, the Supreme Court heard *Amgen Inc. v. Connecticut Retirement Plans & Trust Funds*, which examined whether a class certification should be upheld for a class-action lawsuit accusing the company of failing to disclose drug safety information. The suit alleged that the safety issues were material and subsequently should have been disclosed. Although the ruling centered on the class certification, the case demonstrates the potential for litigation resulting from a failure to accurately describe the safety of certain products in financial reporting.

Value Impact and Timing

The failure to ensure product safety and consistency can negatively impact shareholder value. Problems relating to drug safety and side effects can reduce planned revenues and cash flows, impacting profits and potentially raising the cost of capital. In addition, diminished brand reputation, potential litigation, settlement costs, and fines can present significant liabilities.

Affordability and Fair Pricing

Legislative emphasis in the U.S. and abroad on health care cost containment and increased access will continue to place downward pricing pressures on biotechnology products. As a result, companies that have relied on contractual advantages and reverse payments to protect profits may be challenged to enhance value as efforts to reduce costs gain traction. For example increased scrutiny on existing contracts that prevent institutional buyers such as Medicare from negotiating prices and a new focus on CER could present significant challenges to biotechnology companies. Further, a June, 2013 Supreme Court decision that allows for the Federal Trade Commission to sue companies for antitrust violations if they pay generic manufacturers to delay providing generics is likely to create a significant shift in industry practices. Firms that are able to ensure access and fair pricing are likely to limit the negative impact of cost containment, while recognizing the potential revenue opportunities associated with expanded access.

Evidence

Although the exact impact of the Supreme Court's decision is yet to be determined, it is likely to put increased emphasis on the issue of affordability and fair-pricing. Drug developers may no longer be able to delay generics, which generally cost 15 percent of the brand name's price, and generally capture 90 percent of market share once introduced.^{xiv} The Congressional Budget Office estimates that prohibiting drug originators from paying generic manufacturers in the form of a reverse settlement payment to delay production would save the federal government \$4 billion between 2012 and 2021.^{xv} In addition, three of the biotechnology industry's arthritis drugs with combined annual sales of \$16.9 billion in 2009 will be compared under CER.

Concern over high prices for certain cancer medications led to the formation of a group of over 100 cancer specialists in 2013 who aim to persuade manufacturers to lower prices. The coalition was founded in light of the success that a group of physicians had in getting Sanofi to cut the price of its Zaltrap in half after they refused to use the drug.^{xvi}

Value Impact and Timing

Reliance on anti-competitive practices increases exposure to cost containment efforts and could result in negative impacts on profits as well as cost of capital.

HUMAN CAPITAL

The industry's reliance on human capital is exemplified by the need for attracting, retaining, and ensuring the safety of highly-skilled employees in a competitive market.

Employee Recruitment, Development, and Retention

Biotechnology companies face intense competition for employees. The industry relies on highly skilled employees to develop new products, conduct clinical trials, manage government regulations, and commercialize new products. Firms that are able to attract and retain employees in light of a limited talent pool will be better positioned to protect and enhance shareholder value.

Evidence

Gilead Sciences reports that its "future success will depend in large part on our continued ability to attract and retain highly qualified scientific, technical and management personnel, as well as personnel with expertise in clinical testing, governmental regulation and commercialization." Celgene indicates that the success of its business "depends, in large part, on our continued ability to attract and retain highly qualified management, scientific, manufacturing, and commercial personnel."

Value Impact and Timing

The ability of biotechnology companies to attract and retain talent will likely have a direct impact on profits.

Employee Health and Safety

The biotechnology industry is subject to federal, state, and local regulations regarding workplace safety. Companies must ensure compliance and in many cases exceed current regulations to protect the health and safety of employees who are exposed to hazardous materials, chemicals, viruses and other essential inputs. A failure to manage these risks could result in negative material impacts through litigation, fines, and penalties.

Evidence

Gilead Sciences reports that it uses "hazardous materials, chemicals, viruses and various radioactive compounds in our R&D activities and cannot eliminate the risk of accidental contamination or injury from these materials. Certain misuse or accidents involving these materials could lead to significant litigation, fines and penalties."

The potential for litigation arising from this issue was demonstrated in 2010, when a jury awarded \$1.37 million to a former Pfizer molecular biologist after her employment was allegedly terminated for raising safety concerns.

Value Impact and Timing

The failure to ensure the health and safety of employees can present significant costs and liabilities.

BUSINESS MODEL AND INNOVATION

The biotechnology industry develops products that are essential for the health and well-being of its consumers. Innovation is therefore critical to the value of biotechnology companies. However, the industry does not face material sustainability issues associated with business model and innovation.

GOVERNANCE

Strict regulatory environments and competition in the biotechnology industry increase the importance of strong governance. Management structures must be able to negotiate international laws while avoiding the risks associated with issues such as corruption and bribery. In addition, companies must ensure that policies and practices are in place that allow for effective supply chain management and operational excellence. Information on governance performance is essential for shareholders to understand management quality and a company's ability to protect value.

Corruption and Bribery

Biotechnology firms are subject to various state, federal, and international laws pertaining to health care fraud and abuse. Anti-kickback laws and the U.S. Foreign Corrupt Practices Act generally prohibit companies from making payments for the purpose of obtaining or retaining business. The ability of companies to ensure compliance both in the U.S. and abroad is likely to have material implications.

Evidence

In 2013, Amgen agreed to pay \$24.9 million to settle allegations that it provided kickbacks to pharmacy providers to encourage them to use Aranesp rather than a competing product.^{xvii}

In the closely-related pharmaceutical industry, recent examples of bribery have demonstrated the potential for material impacts on companies that fail to manage this risk. Earlier this year, the Securities and Exchange Commission announced a \$60 million settlement with Pfizer relating to the bribery of doctors and health care workers to increase drug sales.^{xviii} In 2011, Johnson & Johnson agreed to pay \$70 million in fines for similar practices.^{xix}

Value Impact and Timing

Examples of recent bribery settlements demonstrate how these practices can impact both profits and liabilities.

Manufacturing and Supply Chain Quality Management

Manufacturing and supply chain quality are essential to protecting consumer health and corporate value. Biotechnology firms that fail to manage quality in these areas are susceptible to significant fines, lost revenue associated with manufacturing stoppages, and the potential loss of independence. Disclosure of Federal Drug Administration enforcement actions and supply chain audit programs provide shareholders with an understanding of how companies in this industry are managing the associated risks.

Evidence

Heightened concern over the safety and purity of prescription drugs has led the Department of Justice to promise to take an ‘especially hard look’ at the associated manufacturing plants in the U.S. and abroad. This initiative, which represents a shift from FDA oversight of good manufacturing processes, has led to recent civil and criminal settlements for GlaxoSmithKline and Ranbaxy Laboratories of \$750 and \$500 million respectively.^{ix}

In 2012, at least 44 people died and 678 became ill after receiving steroid injections that were produced by New England Compounding Center.^{xi} An investigation determined that the company ignored signs that its ‘clean rooms’

were contaminated, and that it did not take adequate precautions to test the safety of its products. Although this incident and the subsequent bankruptcy involve a privately held company, it illustrates the potential for the significant threat to human health and the erosion of value that can arise when companies involved in the manufacture of drugs fail to ensure operational excellence.

In 2010, Genzyme was required to pay \$175 million in fines due to a consent decree it received for non-compliance at its Allston, MA, facility. The consent decree followed a form 483 in 2008 and a warning letter in 2009. The facility was cited for several violations including the detection of a virus that impairs cell growth in one of the facility’s bioreactors. The company’s manufacturing problems resulted in a limited supply of Fabrazyme, and an effort on the part of patients who relied on the medication to have the federal government abrogate the company’s patent. Genzyme’s operational challenges ultimately contributed to its acquisition by Sanofi in 2011.

Value Impact and Timing

A failure to ensure operational excellence can result in fines, lost revenue associated with plant closures, and a potential loss of operational independence. Therefore companies can experience significant impacts on profits, liabilities, and cost of capital.

SASB INDUSTRY WATCH LIST

The following section provides a brief description of sustainability issues that did not meet SASB's materiality threshold at present, but could have a material impact on the biotechnology industry in the future.

Pharmaceuticals in the Environment

Emerging regulations in the U.S. and abroad coupled with ongoing scientific inquiries suggest increased concern over the issues of pharmaceuticals in the environment. In an effort to reduce the amount of pharmaceuticals that persist in the environment after ingestion or improper disposal, regulatory bodies may extend producer responsibilities. Examples of product take-back regulations continue to surface in the U.S. and abroad, while ongoing science suggests the need for additional

controls on waste water treatment facilities. Although the issue does not currently present a material impact for the industry, biotechnology companies that work to better understand the implications of specific metabolites in the environment are likely to protect shareholder value in advance of future regulations.

Impacts of Climate Change on Human Health

Global climate change has the potential to allow for the spread of diseases that have traditionally been limited to specific geographic areas. Changing weather patterns will present further health care implications through forced population migration and shifts in the availability of water and food. Although climate change does not currently impact corporate valuation in the biotechnology industry, companies that develop innovative strategies to manage the associated risks and opportunities will be well positioned to enhance value.

APPENDIX I: Top Five Companies by Revenue | Biotechnology

- Amgen Inc.
- Gilead Sciences Inc.
- Biogen Idec Inc.
- Celgene Corp.
- Vertex Pharmaceuticals Inc.

APPENDIX II: Evidence of Materiality | Biotechnology

The following table provides a summary of the evidence of materiality for each issue in the biotechnology industry.

MATERIAL SUSTAINABILITY ISSUES		EVIDENCE OF INTEREST				EVIDENCE OF FINANCIAL IMPACT				FORWARD-LOOKING IMPACT				
		MM	IWGs		Other	EI	Revenue / Cost	Asset/ Liability	Cost of Capital	EFI	Probability	Magnitude	Timing	FLI
			%	Priority										
ENVIRONMENTAL CAPITAL	Energy, Water, & Waste Efficiency	40%	78%	7		Low	•			Low	•	•	Near	Yes
SOCIAL CAPITAL	Safety of Clinical Trial Participants	50%	78%	2		Med	•	•		High				
	Ethical Marketing	60%	100%	3		High	•			Low				
	Access to Medicines	35%	89%	4	•	Med				Low	•	•	Near	Yes
	Affordability and Fair Pricing	60%	78%	5		Low	•		•	Med	•	•	Near	Yes
	Drug Safety and Side Effects	100%	89%	1		High	•	•	•	High				
	Counterfeit Drugs	100%	-	-	•	High	•	•		Med	•	•	Near	Yes
HUMAN CAPITAL	Employee Recruitment, Development, and Retention	35%	56%	8	•	Low	•			Low				
	Employee Health and Safety	70%	-	-	•	Low	•	•		Low				
GOVERNANCE	Corruption and Bribery	75%	100%	6		High	•	•		Med				
	Manufacturing and Supply Chain Management	35%	-	-	•	Med	•	•	•	High				

EMERGING SUSTAINABILITY ISSUES		EVIDENCE OF INTEREST				EVIDENCE OF FINANCIAL IMPACT				FORWARD-LOOKING IMPACT				
		MM	IWGs		Other	EI	Revenue / Cost	Asset/ Liability	Cost of Capital	EFI	Probability	Magnitude	Timing	FLI
			%	Priority										
ENVIRONMENTAL CAPITAL	Pharmaceuticals in the Environment	40%	56%	9	•	No				No	•	•	Near	Yes
	Impact of Climate Change on Human Health	35%	56%	10		No				No	•	•	long	Yes

MM: Materiality Map, a percentile score of the relative importance of the issue among SASB's initial list of 43 generic sustainability issues. The score is based on the frequency of relevant keywords in documents (i.e., 10-Ks, shareholder resolutions, legal news, news articles, and corporate sustainability reports) that are available on the Bloomberg terminal for the industry's publicly listed companies.

IWGs: SASB Industry Working Groups

%: The percentage of IWG participants that found the issue to be material. (-) denotes that the issue was added after the IWG was convened.

Priority: Average ranking of the issue in terms of importance. One denotes the most material issue. (-) denotes that the issue was added after the IWG was convened.

Other: Other evidence of interest including: in-depth 10-k analysis, shareholder resolutions, corporate sustainability reports, traditional financial analysis, impending regulation, and academic studies. This is primarily used in cases where the issue was added after the IWG or the issue received lower MM and IWG scores. However, this test is also used in some cases where there is significant additional evidence of interest.

EI: Evidence of Interest, a subjective assessment based on quantitative and qualitative findings.

EFI: Evidence of Financial Impact, a subjective assessment based on quantitative and qualitative findings.

FLI: Forward Looking Impact, a subjective assessment on the presence of a material forward-looking impact

APPENDIX III: Sustainability Accounting Metrics | Biotechnology

The following table provides a list of sustainability issues and the associated accounting metrics for the biotechnology industry.

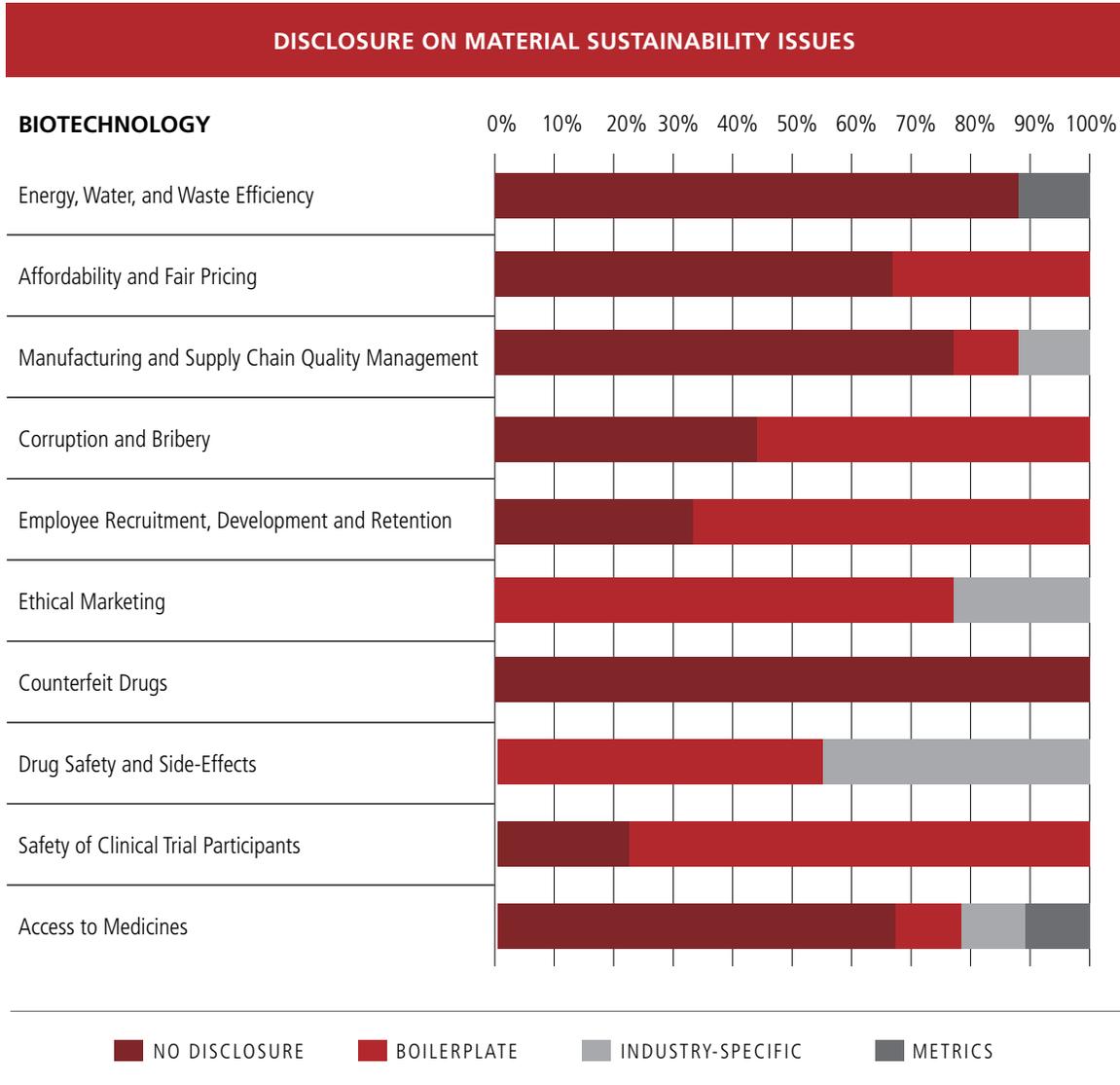
TOPIC	CODE	ACCOUNTING METRIC
Access to Medicines	HC0101-01	Description of initiatives to promote access to health care products in priority countries as defined by the Access to Medicine Index.
	HC0101-02	List of products on the WHO List of Prequalified Medicinal Products as part of its Prequalification of Medicines Programme (PQP).
Drug Safety and Side Effects	HC0101-03	List of products listed in the FDA's MedWatch Safety Alerts for Human Medical Products (Drugs and Therapeutic Biological Products) database, including those products with Potential Signals of Serious Risks or that have New Safety Information identified by the FDA Adverse Event Reporting System (FAERS).
	HC0101-04	Number of fatalities associated with products as reported in the FDA Adverse Event Reporting System.
	HC0101-05	List of products recalled.
	HC0101-06	Description of product stewardship initiatives to promote take-back and redistribution or safe permanent disposal of unused product at the end of its lifecycle. Where applicable: (1) amount of direct funding for such initiatives and (2) amount of product (by weight) accepted for take-back, reuse, or disposal.
Safety of Clinical Trial Participants	HC0101-07	Discussion, by world region, of management process for ensuring quality and patient safety during clinical trials, including those conducted with third-party clinical research organizations (CROs). Description of processes for obtaining informed consent, of incentives offered to participants, and of any clinical trials terminated due to failure to follow good clinical practice standards.
	HC0101-08	Number of FDA Clinical Investigator Inspections of investigators used for clinical trials during the past year that resulted in: (1) Voluntary Action Indicated (VAI) and (2) Official Action Indicated (OAI).
	HC0101-09	Description of legal and regulatory fines and settlements associated with clinical trials in World Bank Low-income and Lowermiddle-income Countries (LICs and LMICs) and UN HDI Medium-High Development Countries (MHDCs) that are not captured by the World Bank's LIC or LMIC rankings. Dollar amount of fines and settlements and a description of corrective actions implemented in response to events.
Affordability and Fair Pricing	HC0101-10	Number of settlements of Abbreviated New Drug Application (ANDA) litigation that involved payments and/or provisions to delay bringing an authorized generic product to market for a defined time period.
	HC0101-11	Ratio of weighted average rate of net price increases (for all products) to the annual increase in the U.S. Consumer Price Index.
Ethical Marketing	HC0101-12	Description of legal and regulatory fines and settlements associated with false marketing claims, including Federal Food, Drug, and Cosmetic Act violations for off-label marketing prosecuted under the False Claims Act. Dollar amount of fines and settlements and a description of corrective actions implemented in response to events.
	HC0101-13	Description of code of ethics governing promotion of off-label use of products, including mechanisms to ensure compliance.

APPENDIX III: Sustainability Accounting Metrics | Biotechnology (Cont.)

TOPIC	CODE	ACCOUNTING METRIC
Employee Recruitment, Development, and Retention	HC0101-14	Description of talent recruitment and retention efforts for scientists and other research and development (R&D) personnel, such as mentorship and career development programs, leadership training, or unique incentive structures.
	HC0101-15	Training and development expenditures per full time employee by: (1) expenditures for industry or professional qualification and advanced industry education; (2) all other.
	HC0101-16	Employee turnover by voluntary and involuntary for: Executives/Senior Managers, Mid-level Managers, Professionals, All others (EEO-1 categories: technicians, sales, admin support, service workers).
Employee Health and Safety	HC0101-17	Total Injury Rate – (Number of recordable injuries and illnesses / Hours Worked)*200,000.
	HC0101-18	Days Away, Restricted, or Transferred (DART) rate – (Number of recordable injuries and illnesses resulting in days away from work, restricted work activity, or job transfers / Hours Worked)*200,000.
	HC0101-19	Laboratory-acquired infection (LAI) rate – LAIs per 1000 employees in human and animal diagnostic laboratories.
Counterfeit Drugs	HC0101-20	Description of methods and technologies used to maintain traceability of products throughout the supply chain and prevent counterfeiting.
	HC0101-21	Description of process for alerting end customers and business partners of potential or known risks associated with counterfeit products.
	HC0101-22	Number (and description) of actions that led to raids, seizure, arrests, and/or filing of criminal charges related to counterfeit products. .
Energy, Water, and Waste Efficiency	HC0101-23	Total annual energy consumed (gigajoules) and percentage renewable (e.g., wind, biomass, solar).
	HC0101-24	Total water withdrawals and percentage in water-stressed regions – High or Extremely High Baseline Water Stress as defined by the WRI Water Risk Atlas; percentage of process water recycled.
	HC0101-25	Overall Process Mass Intensity (PMI) and PMI broken down for water and organic solvents, where PMI = quantity of raw materials input (kg) / quantity of active pharmaceutical product (API) output (kg).
	HC0101-26	Amount of waste (metric tons); percentage that is recycled, incinerated (including for energy recovery), and landfilled.
Corruption and Bribery	HC0101-27	Description of legal and regulatory fines and settlements associated with bribery, corruption, or other unethical practices. Dollar amount of fines and settlements and a description of corrective actions implemented in response to events.
	HC0101-28	Description of code of ethics governing interactions with health care professionals, including mechanisms to ensure employee compliance.
Manufacturing and Supply Chain Quality Management	HC0101-29	Description of FDA enforcement actions taken in response to violations of current good manufacturing practices (cGMP), including: product deemed adulterated, form 483s, suggested recall (Class I, II, III), Warning Letters, Border Alerts, license suspension or revocation, product seizure, Consent Decrees, criminal prosecution. Description of corrective actions implemented in response to actions.
	HC0101-30	Percentage of facilities and Tier I suppliers participating in the Rx-360 International Pharmaceutical Supply Chain Consortium audit program or equivalent third-party audit programs for integrity of supply chain and ingredients (e.g., APIs, chemical, raw material, excipients, etc.).

APPENDIX IV: Analysis of 10-K Disclosures | Biotechnology

The following graph demonstrates an aggregate assessment of how the top ten companies in the biotechnology industry are currently reporting on material sustainability issues in the Form 10-K. The analysis was completed prior to the finalization of the issues, so the graph does not reflect disclosure on all issues.



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