SUSTAINABILITY ACCOUNTING STANDARD | HEALTH CARE SECTOR

BIOTECHNOLOGY

Sustainability Accounting Standard

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Sustainability Accounting
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BIOTECHNOLOGY

Sustainability Accounting Standard

About SASB

The Sustainability Accounting Standards Board (SASB) provides sustainability accounting standards for use by publicly-listed corporations in the U.S. in disclosing material sustainability issues for the benefit of investors and the public. SASB standards are designed for disclosure in mandatory filings to the Securities and Exchange Commission (SEC), such as the Form 10-K and 20-F. SASB is an independent 501(c)3 non-profit organization and is accredited to set standards by the American National Standards Institute (ANSI).

SASB is developing standards for more than 80 industries in 10 sectors. SASB's standards-setting process includes evidence-based analysis with in-depth industry research and engagement with a broad range of stakeholders. The end result of this process is the creation of a complete, industry-specific accounting standard which accurately reflects the material issues for each industry.

SUSTAINABILITY ACCOUNTING STANDARDS BOARD

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INTRODUCTION

Purpose and Structure

This document contains the SASB Sustainability Accounting Standards (SASB Standards) for Biotechnology.

SASB Standards are comprised of **(1) disclosure guidance and (2) accounting standards on sustainability topics** for use by U.S. and foreign public companies in their annual filings (Form 10-K or 20-F) with the U.S. Securities and Exchange Commission (SEC). To the extent relevant, SASB Standards may also be applicable to other periodic mandatory fillings with the SEC, such as the Form 10-Q, Form S-1, and Form 8-K.

SASB's **disclosure guidance** identifies sustainability topics at an industry level and—depending on the specific operating context of a company—may be material to a company within that industry. Each company is ultimately responsible for determining which information is material, and which such company is therefore required to include in its Form 10-K or 20-F and other periodic SEC filings.

SASB's **accounting standards** provide companies with standardized accounting metrics to account for performance on industry-level sustainability topics. When making disclosure on sustainability topics, companies adopting SASB's accounting standards will help to ensure that disclosure is standardized and therefore useful, relevant, comparable and auditable.

Guidance for Disclosure of Material Sustainability Topics in SEC filings

1. Industry-Level Material Sustainability Topics

For the Biotechnology Industry, SASB has identified the following material sustainability topics:

- **Access to Medicines**
- **Drug Safety and Side Effects**
- **Safety of Clinical Trial Participants**
- **Affordability and Fair Pricing**
- **Ethical Marketing**
- **Employee Recruitment, Development and Retention**
- **Employee Health and Safety**
- **Counterfeit Drugs**
- **Energy, Water, and Waste Efficiency**
- **Corruption and Bribery**
- **Manufacturing and Supply Chain Quality Management**

NOTE: A description of each topic is provided alongside standard accounting metrics in the rest of this document.

2. Company-Level Determination and Disclosure of Material Sustainability Topics

Sustainability disclosures are governed by the same laws and regulations that govern disclosures by securities issuers generally. According to the U.S. Supreme Court, a fact is material if, in the event such fact is omitted from a particular disclosure, there is "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 the information made available".[1]

SASB has attempted to identify those sustainability topics (above) that it believes may be material for all companies within the Biotechnology Industry. SASB recognizes, however, that each company is ultimately responsible for determining what is material to it.

Regulation S-K, which sets forth certain disclosure requirements associated with Form 10-K and other SEC filings, requires companies, among other things, to describe in the Management's Discussion and Analysis of Financial Condition and Results of Operations (MD&A) section of Form 10-K "any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations. If the registrant knows of events that will cause a material change in the relationship between costs and revenues (such as known future increases in costs of labor or materials or price increases or inventory adjustments), the change in the relationship shall be disclosed."[2]

Furthermore, Instructions to Item 303 state that the MD&A "shall focus specifically on material events and uncertainties known to management that would cause reported financial information not to be necessarily indicative of future operating results or of future financial condition."

In determining whether a trend or uncertainty should be disclosed, the SEC has stated that management should use a two-part assessment based on probability and magnitude:

- First, a company is not required to make disclosure about a known trend or uncertainty if its management determines that such trend or uncertainty is not reasonably likely to occur.
- If a company's management cannot make a reasonable determination of the likelihood of an event or uncertainty, then disclosure is required unless management determines that a material effect on the registrant's financial condition or results of operation is not reasonably likely to occur.

3. Sustainability Accounting Standard Disclosures in Form 10-K

a. Management's Discussion and Analysis

Companies should consider making disclosure on sustainability topics as a complete set in the MD&A, in a sub-section titled **"Sustainability Accounting Standards Disclosures."**[3]

b. Other Relevant Sections of Form 10-K

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[1] TSC Industries v. Northway, Inc., 426 U.S. 438 (1976).

[2] 17 C.F.R. 229.303(Item 3030)(a)(3)(ii).

[3] SEC [Release Nos. 33-8056; 34-45321; FR-61] Commission Statement about Management's Discussion and Analysis of Financial Condition and Results of Operations: "We also want to remind registrants that disclosure must be both useful and understandable. That is, management should provide the most relevant information and provide it using language and formats that investors can be expected to understand. Registrants should be aware also that investors will often find information relating to a particular matter more meaningful if it is disclosed in a single location, rather than presented in a fragmented manner throughout the filing."

In addition to the MD&A section, companies should consider disclosing sustainability information in other sections of Form 10-K, as relevant, including:

- **Description of business**—Item 101 of Regulation S-K requires a company to provide a description of its business and its subsidiaries. Specifically Item 101(c)(1)(xii) expressly requires disclosure regarding certain costs of complying with environmental laws:

  Appropriate disclosure also shall be made as to the material effects that compliance with Federal, State and local provisions which have been enacted or adopted regulating the discharge of materials into the environment, or otherwise relating to the protection of the environment, may have upon the capital expenditures, earnings and competitive position of the registrant and its subsidiaries.

- **Legal proceedings**—Item 103 of Regulation S-K requires companies to describe briefly any material pending or contemplated legal proceedings. Instructions to Item 103 provide specific disclosure requirements for administrative or judicial proceedings arising from laws and regulations targeting discharge of materials into the environment or primarily for the purpose of protecting the environment.

- **Risk factors**—Item 503(c) of Regulation S-K requires filing companies to provide a discussion of the most significant factors that make an investment in the registrant speculative or risky, clearly stating the risk and specifying how a particular risk affects the particular filling company.

- **Rule 12b-20**—Securities Act Rule 408 and Exchange Act Rule 12b-20 require a registrant to disclose, in addition to the information expressly required by law or regulation, "such further material information, if any, as may be necessary to make the required statements, in light of the circumstances under which they are made, not misleading."

More detailed guidance on disclosure of material sustainability topics can be found in the **SASB Conceptual Framework**, available for download via http://www.sasb.org/approach/conceptual-framework/

Guidance on Accounting of Material Sustainability Topics

For material sustainability topics in the Biotechnology Industry, SASB identified the accounting metrics below in **Table 1. Material Sustainability Topics & Accounting Metrics.**

SASB recommends that each company consider using these sustainability accounting metrics when disclosing their performance with respect to each of the sustainability topics it has identified as material.

As appropriate—and consistent with Rule 12b-20[4] —for each sustainability topic, companies should consider including a narrative description of any material factors necessary to ensure completeness, accuracy and comparability of the data reported. Where not addressed by the specific accounting metrics, but relevant, the registrant should discuss the following related to the topic:

[4] SEC Rule 12b-20: "In addition to the information expressly required to be included in a statement or report, there shall be added such further material information, if any, as may be necessary to make the required statements, in the light of the circumstances under which they are made not misleading."

- the registrant's **strategic approach** to managing performance on material sustainability issues;
- the registrant's **competitive positioning**;
- the **degree of control** the registrant has;
- any **measures the registrant has undertaken** or **plans to undertake** to improve performance; and
- data for registrant's **last three completed fiscal years** (when available).

SASB recommends that registrants use SASB Standards specific to their primary industry as identified in the Sustainability Industry Classification System (SICS™). If a registrant generates significant revenue from multiple industries, SASB recommends that it consider the materiality of the sustainability issues that SASB has identified for those industries and disclose the associated SASB accounting metrics.

Users of the SASB Standards

The SASB Standards are intended for companies that engage in public offerings of securities registered under the Securities Act of 1933 (the Securities Act) and those that issue securities registered under the Securities Exchange Act of 1934 (the Exchange Act)[5], for use in SEC filings, including, without limitation, annual reports on Form 10-K (Form 20-F for foreign issuers), quarterly reports on Form 10-Q, current reports on Form 8-K, and registration statements on Forms S-1 and S-3. Nevertheless, disclosure with respect to the SASB Standards is not required or endorsed by the SEC or other entities governing financial reporting, such as FASB, GASB, or IASB.

Scope of Disclosure

Unless otherwise specified, SASB recommends:

- That a registrant disclose on sustainability issues and metrics for itself and for entities in which the registrant has a controlling interest and therefore are consolidated for financial reporting purposes (controlling interest is generally defined as ownership of 50% or more of voting shares);[6]
- That for consolidated entities, disclosures be made, and accounting metrics calculated, for the whole entity, regardless of the size of the minority interest; and
- That information from unconsolidated entities not be included in the computation of SASB accounting metrics. A registrant should disclose, however, information about unconsolidated entities to the extent that such registrant considers the information necessary for investors to understand its performance with respect to sustainability issues (typically this disclosure would be limited to risks and opportunities associated with these entities).

[5] Registration under the Securities Exchange Act of 1934 is required (1) for securities to be listed on a national securities exchange such as the New York Stock Exchange, the NYSE Amex and the NASDAQ Stock Market or (2) if (A) the securities are equity securities and are held by more than 2,000 persons (or 500 persons who are not accredited investors) and (B) the company has more than $10 million in assets.

[6] See US GAAP consolidation rules (Section 810).

Reporting Format

Normalization

SASB recognizes that normalizing accounting metrics is important for the analysis of SASB disclosures.

SASB recommends that a registrant disclose any basic operational data that may assist in the accurate evaluation and comparability of disclosure, to the extent that they are not already disclosed in the Form 10-K (e.g., revenue, EBITDA, etc.).

Such data may include high-level operating data such as total number of employees, quantity of products produced or services provided, number of facilities, or number of customers. It may also include industry-specific data such as plant capacity utilization (e.g., for specialty chemical companies), number of transactions (e.g., for internet media and services companies), hospital bed days (e.g., for health care delivery companies), or proven and probable reserves (e.g., for oil and gas exploration and production companies).

Any operational data provided should:

- Convey contextual information that would not otherwise be apparent from SASB accounting metric
- Be deemed generally useful for users of SASB accounting metrics (e.g., investors) in performing their own calculations and creating their own ratios.

Units of Measure

Unless specified, disclosures should be reported in International System of Units (SI units).

Uncertainty

SASB recognizes that there may be inherent uncertainty when disclosing certain sustainability data and information. This may be related to variables like the imperfectness of third-party reporting systems or the unpredictable nature of climate events. Where uncertainty around a particular disclosure exists, SASB recommends that the registrant should consider discussing its nature and likelihood.

Estimates

SASB recognizes that scientifically-based estimates, such as the reliance on certain conversion factors or the exclusion of de *minimis* values, may be necessary for certain quantitative disclosures. Where appropriate, SASB does not discourage the use of such estimates. When using an estimate for a particular disclosure, SASB expects that the registrant discuss its nature and substantiate its basis.

Timing

Unless otherwise specified, disclosure shall be for the registrant's fiscal year.

Limitations

There is no guarantee that SASB Standards to address all sustainability impacts or opportunities associated with a sector, industry, or company and, therefore, a company must determine for itself the topics—sustainability-related or otherwise—that warrant discussion in a registrant's SEC filings.

Disclosure under SASB Standards is voluntary. It is not intended to replace any legal or regulatory requirements that may be applicable to user operations. Where such laws or regulations address legal or regulatory topics, disclosure under SASB Standards is not meant to supersede those requirements. Disclosure according to SASB Standards shall not be construed as demonstration of compliance with any law, regulation, or other requirement.

SASB Standards are intended to be aligned with the principles of materiality enforced by the SEC. However, SASB is not affiliated with or endorsed by the SEC or other entities governing financial reporting, such as FASB, GASB, or IASB.

Forward Looking Statements

Disclosures on sustainability topics can involve discussion of future trends and uncertainties related to the registrant's operations and financial condition, including those influenced by external variables (e.g., environmental, social, regulatory and political). Companies making such disclosures should familiarize themselves with the safe harbor provisions of Section 27A of the Securities Act and Section 21E of the Exchange Act, which preclude civil liability for material misstatements or omissions in such statements if the registrant takes certain steps, including, among other things, identifying the disclosure as forward looking and accompanying such disclosure with "meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statements."

Assurance

In reporting on SASB Standards, it is expected that registrants report with the same level of rigor, accuracy, and responsibility as all other information contained in their SEC filings.

SASB recommends registrants use a higher level of assurance (attestation), such as an Examination Engagement to AT Section 701.

The following sections contain the technical protocols associated with each accounting metric such as guidance on definitions, scope, accounting guidance, compilation, and presentation.

The term "shall" is used throughout this Standard to indicate those elements that reflect SASB's mandatory disclosure requirements. The terms "should" and "may" are used to indicate guidance, which, although not mandatory, provides a recommended means of disclosure.

Table 1. Material Sustainability Topics & Accounting Metrics

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.
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).

Table 1. Material Sustainability Topics & Accounting Metrics (cont.)

TOPIC	CODE	ACCOUNTING METRIC
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 business practices, including violations of the Foreign Corrupt Practices Act and those associated with providing kickbacks to physicians. 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.).

Access to Medicines

Description

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.

Accounting Metrics

HC0101-01. Description of initiatives to promote access to health care products in priority countries as defined by the Access to Medicine Index.

.01 Disclosure applies to initiatives the registrant, launched, funded, supported, or otherwise participated in during the fiscal year that related to improving access to health care in priority countries. A product shall be discussed if it was authorized for sale and available during the fiscal year. Initiatives shall be discussed if implementation was ongoing during the fiscal year. Initiatives that began or concluded during the fiscal year may be discussed; the registrant, however, should indicate this condition.

.02 The following issues as they relate to access to health care initiatives may be relevant for the registrant to discuss: research and development, pricing, public policy and market influence efforts, manufacturing and distribution, patents and licensing, product donations, and philanthropic activities.

.03 The Access to Medicine Foundation considers the priority issues and diseases in priority countries to be those with the highest Disability Adjusted Life Years (DALY) based on WHO data. These include communicable, non-communicable, neglected tropical diseases, neonatal infections, and maternal health conditions. A full list is on page 17 of the Access to Medicine Index Methodology 2012.

.04 Initiatives discussed should focus on the aforementioned diseases and conditions. The registrant may discuss additional or alternative diseases and conditions but should provide evidence that they are considered a priority in the priority countries discussed.

.05 Priority countries comprise those that meet the following definition: (1) Low-income and Lowermiddle-income Countries (LICs and LMICs) based on World Bank classifications (updated in July 2011) or (2) UN HDI Medium-High Development Countries (MHDCs) (updated in 2011) that are not automatically captured by the World Bank LIC or LMIC rankings. The full list of countries included is on Page 14 of Access to Medicine Index Methodology 2012.

NOTES

HC0101-1 – Priority diseases include: the top 10 communicable diseases based on Disability Adjusted Life Years (DALY) from the WHO Global Burden of Disease; the top 10 non-communicable diseases based on DALYs from the WHO Global Burden of Disease; 14 of the WHO Neglected Tropical Diseases. A full list is in on page 17 of the Access to Medicine Index Methodology 2012.

HC0101-02. List of products on the WHO List of Prequalified Medicinal Products as part of its Prequalification of Medicines Programme (PQP).

.06 Using the WHO List of Prequalified Medicinal Products (publicly accessible here), the registrant shall conduct a search within the "Applicant" field for the registrant and count all products listed by International Nonproprietary Name (INN).

.07 Multiple listings of the same active pharmaceutical product (API) in different strengths (e.g., 30 mg and 20 mg) shall be counted once. Multiple listings of the same API in different formulations (e.g., tablet and capsule) shall be counted once. Listings of single APIs (e.g., Lamivudine) and combinations of the same API with one or more additional APIs (e.g., Lamivudine + Stavudine) shall be counted separately but following guidance for multiple strengths and formulations. Products listed under the status "Suspended" shall not be counted.

.08 An itemized list should be provided of products by International Nonproprietary Name (INN), including brand name(s) in parentheses where applicable. The registrant may also choose to disclose the number of its products targeting each WHO-defined therapeutic area: Diarrhoea, HIV/AIDS, Influenza, Malaria, Reproductive Health, and Tuberculosis.

.09 Disclosure applies to products manufactured and/or marketed by the registrant during the fiscal year. A product should be discussed if it was authorized for sale and available during the fiscal year. Initiatives should be discussed if implementation was ongoing during the fiscal year.

Drug Safety and Side Effects

Description

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 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.

Accounting Metrics

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).

.10 The registrant should access the publicly available list of Safety Alerts for Human Medical Products issued as part of the FDA's MedWatch Safety Information and Adverse Event Reporting Program by navigating to the "Safety Alerts for Human Medical Products" subsection of the "Safety Information" section of the "MedWatch: The FDA Safety Information and Adverse Event Reporting Program" page, here.

.11 The safety alerts are organized into four categories: (1) Drugs and Therapeutic Biological Products, (2) Medical Devices, (3) Special Nutritional and Cosmetic Products, and (4) Products with Undeclared Drug Ingredients.

.12 The registrant should review the Product Names on the Drugs and Therapeutic Biological Products and disclose all listings associated with the registrant. This includes trade names for which the registrant has patents or active ingredients or classes of product that it manufactures and markets.

.13 Additionally, the registrant should access the publicly available list of products for which the FDA staff in the Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) have identified potential safety issues. The registrant should access the quarterly reports via www.fda.gov by navigating to the "Potential Signals of Serious Risks/New Safety Information Identified from the FDA Adverse Event Reporting System (FAERS) (formerly AERS)" page under the FDA Adverse Event Reporting System (FAERS) page, here.

NOTES

HC0101-03 – MedWatch is the Food and Drug Administration's mechanism for consumers and health professionals to report serious adverse event, product quality problem, product use error, therapeutic inequivalence/failure, or suspected counterfeit medical products associated with FDA-regulated drug, biologic, medical device, dietary supplement, or cosmetic products.

The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's post-marketing safety surveillance program for drug and therapeutic biologic products. The informatic structure of the FAERS database adheres to the international safety reporting guidance issued by the International Conference on Harmonisation (ICH E2B). Adverse events and medication errors are coded to terms in the Medical Dictionary for Regulatory Activities (MedDRA) terminology.

Additional references:

- Instructions for Completing Form FDA 3500A
- MedWatch Online Voluntary Reporting Form (3500)

.14 Products are listed by "active ingredient and trade name (if applicable)" or by "product class."

.15 The registrant shall disclose all listings associated with the registrant. This includes trade names for which the registrant has patents and active ingredients or classes of product that it manufactures and markets.

.16 If the registrant manufactures a product with an active ingredient or a product in a product class listed in the database but has evidence that the listing does not apply to its specific products, it shall provide such evidence.

HC0101-04. Number of fatalities associated with products as reported in the FDA Adverse Event Reporting System.

.17 Registrants should access the ASCII or SGML data files that are publicly available through "The FDA Adverse Event Reporting System (FAERS): Latest Quarterly Data Files" system by navigating to the "The FDA Adverse Event Reporting System (FAERS): Latest Quarterly Data Files" page under the "FDA Adverse Event Reporting System (FAERS)" page, here.

.18 Data files are summarized and reported quarterly; the registrant should download and access files covering its entire fiscal year. Files can be viewed by creating a relational database using applications such as ORACLE®, Microsoft Office Access, MySQL® and IBM DB2 or SAS® analytic tools.

.19 The registrant should open the quarterly files "DEMOyyQq.TXT," which contains patient demographic and administrative information for each event report, including the manufacturer of the drug or biologic product associated with the event.

.20 The registrant should query the database column "MFR_SNDR," which contains the verbatim name of the manufacturer that submitted each report. Because the database is a verbatim record of submittals, the registrant must ensure that its query accounts for any and all variations and abbreviations of its name. Furthermore, it must account for the fact that the database does not allow for special characters or symbols such as ampersand ("&") and replaces them with a period (".").

.21 The registrant should record all Individual Safety Report (ISR) numbers for entries associated with it; the ISR number uniquely identifies an AERS report and is the primary link field between data files.

.22 Finally, the registrant should open the quarterly Outcome files "OUTCyyQq.TXT" and query all ISR numbers associated with it that have an outcome code of "DE" for death/fatality.

.23 Using the "The FDA Adverse Event Reporting System (FAERS): Latest Quarterly Data Files" system, the registrant shall disclose the absolute number of fatalities associated with all drugs and biologic products it manufactures. The registrant shall disclose all fatalities that occurred during the fiscal year for which it is disclosing, even if the adverse event began in a prior period.

HC0101-05. List of products recalled

.24 A recall is an action taken by a registrant to remove a product from the market. Recalls may be conducted voluntarily by a registrant, or they may be mandatory and initiated by FDA request or by FDA order under statutory authority. Registrants shall disclose each type of recall.

.25 Registrants should review the weekly Enforcement Reports published by the FDA, which are publicly available on the "Recalls, Market Withdrawals, & Safety Alerts" subsection of the FDA's "Safety" webpage. The registrant may access the list of recalls via www.fda.gov, by navigating to the "Enforcement Reports" subsection of the "Recalls, Market Withdrawals, & Safety Alerts" section of the FDA's "Safety" page, here.

.26 The registrant shall also disclose recalls in foreign markets that have been initiated voluntarily, at the request of a foreign national regulatory authority, or by order of a foreign national regulatory authority under statutory authority. The registrant shall also disclose recalls initiated voluntarily that have not been reported to the FDA (or national regulatory authority) and/or are not listed in an FDA Enforcement Report. national regulatory authority) and/or are not listed in an FDA Enforcement Report.

.27 For FDA-initiated recalls, the registrant may choose to disclose the FDA classification of each recall: Class I, Class II, or Class III.

.28 For each recalled product, the registrant may choose to disclose revenues from the twelve months prior to the date of recall. This twelve-month period may extend beyond the fiscal year for which the registrant is disclosing; the figure is intended to indicate annual revenues associated with the product so that the financial impact of the recall can be gauged.

.29 If a recall relates to only a subset of a product (e.g., specific lots or a particular style) then the registrant should indicate the scope of the recall; and, if the registrant is disclosing revenue associated with the recall, it should be limited to the portion of the product affected by the recall.

.30 The registrant should list recalls associated with all drugs and biologic products manufactured by the registrant and its subsidiaries.

NOTES

HC0101-05

Definitions

Class I recall: a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.

Class II recall: a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

Class III recall: a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

Additional references:
- Chapter 7 Recall Procedures (FDA Regulatory Procedures – July 2012)

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.

.31 The registrant shall discuss systemic efforts related to end-of-life management of its products, including those intended to preventing black-market sales, abuse, and release into the environment.

.32 Unused product includes that which is expired, unwanted, waste, or excess. Product take-back includes reclaiming unused products from end-consumers or medical facilities for redistribution or disposal. Biopharmaceutical reuse programs would include redistribution initiatives aimed at providing medication to underserved populations, subject to state or local laws. Safe permanent disposal of biopharmaceutical products often involves high-temperature incineration and must be conducted in accordance with federal or state laws governing management of unused pharmaceuticals, such as the Controlled Substance Act, the Resource Conservation and Recovery Act (RCRA), the Centers for Medicare & Medicaid Services (CMS), and the Health Insurance Portability and Accountability Act (HIPAA).

.33 Direct funding of initiatives includes programs or initiatives that are financially supported and administered by the registrant as well as initiatives funded by the registrant that are administered by third parties for the express purpose of product take-back. The registrant should disclose expenditures in dollars for the fiscal year.

.34 The registrant shall disclose the amount of product (in metric tons) that is accepted through the initiatives. For initiatives that are co-funded by the registrant, it shall prorate the amount of product accepted for take-back by its percentage contribution to the funding of the initiative.

Safety of Clinical Trial Participants

Description

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.

Accounting Metrics

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.

.35 Registrant shall describe its oversight of CROs' quality and safety systems, such as the type of procedures followed (e.g., if it is proprietary to the registrant, developed by the CRO, and/or it follows established third-party guidelines), use and frequency of audits or inspections, and enforcement mechanisms.

.36 As outlined by the U.S. Department of Health and Human Services, informed consent requires more than legally effective acceptance of participation in a clinical trial – it also involves, on the part of the registrant, (1) disclosing to potential research subjects information needed to make an informed decision; (2) facilitating the understanding of what has been disclosed; and (3) promoting the voluntariness of the decision about whether or not to participate in the research.

.37 A Clinical Research Organization or Contract Research Organization (CRO) is a scientific organization (commercial, academic or other) to which the registrant has transferred some of its tasks and obligations as a sponsor.

.38 Registrant shall disclose the management process for CROs, broken down by the following world regions: North America, Central and Latin America, Asia (including the Middle East), and Africa.

.39 The registrant should describe the nature and terms of monetary incentives that it uses or that are used by CROs with which it contracts. Reimbursements for meal, travel, or lodging should not be discussed.

.40 Additionally, the registrant shall list all trials, conducted by the registrant (including those outsourced to third parties such as CROs), that were terminated for failure to follow good clinical practice standards.

.41 Good Clinical Practice (GCP) are defined and regulated by the U.S. Food and Drug Administration and through International CGP guidance that has been adopted by the FDA.

.42 The registrant shall list all clinical trials terminated – whether the decision was made by investigator(s) or the study sponsor, and whether it was made with or without the input of a Data Monitoring Committee (DMC).

.43 Disclosure should not include clinical trials terminated for reasons other than those related to GCP, such as reallocation of funding, loss of personnel, failure to meet study benchmarks, lack of participants, etc.

.44 Scope: The registrant should discuss its management process with respect to all CROs it has worked with during the past fiscal year or with which it has worked with in the past and plans to work with in the future.

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 and (2) Official Action Indicated.

.45 Registrant should access the publicly available Clinical Investigator Inspection Search via the "Drug Approvals and Databases" page on the FDA's "Drugs" site. The current link is here.

.46 Registrants should search the database for inspections of investigators that they have used for clinical trials during the fiscal year. The FDA's Clinical Investigator Inspection List (CLIIL) is organized by individual investigators (i.e., individual persons at research locations); however, a search can be conducted by "location" for the name – or variations of the name – of the registrant's facilities or Clinical Research Organizations (CROs) it uses.

.47 The registrant shall disclose inspections of investigators that conducted clinical trials for the registrant or on behalf of the registrant (such as at a CRO).

.48 The registrant shall disclose the number of inspections that resulted in a classification of Voluntary Action Indicated (VAI) or Official Action Indicated (OAI), as listed in the "Classification" column.

.49 Scope: The registrant shall disclose VAIs and OAIs issued to investigators who participated in the registrant's or its subsidiaries' clinical trials during the past year. This includes investigators working on behalf of the registrants or its subsidiaries at a CRO.

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.

.50 The registrant shall briefly describe the nature and context of fines and settlements associated with clinical trials in the specified countries, including civil actions (e.g., civil judgment, settlements or regulatory penalties) and criminal actions (e.g., criminal judgment, penalties or restitutions) taken by any entity (government, businesses, or individuals).

.51 The registrant shall disclose the amount of any fine or settlement associated with each incident, not including legal fees.

.52 The registrant shall describe any corrective actions it has implemented as a result of each incident. This may include, but is not limited to, specific changes in operations, management, processes, products, business partners, training, or technology.

.53 The scope of countries comprises those that meet the following definition: (1) Low-income and Lowermiddle-income Countries (LIC and LMICs) based on World Bank classifications, updated in July 2011, or (2) UN HDI Medium-High Development Countries (MHDCs) (updated in 2011) that are not automatically captured by the World Bank LIC or LMIC rankings. A current, full list of countries within the scope of disclosure is on page 14 of Access to Medicine Index Methodology 2012.

NOTES

HC0101-08

Definitions

Voluntary Action Indicated – Objectionable conditions were found but the problems do not justify further regulatory action. Any corrective action is left to the investigator to take voluntarily.

Official Action Indicated – Official Action Indicated. Objectionable conditions were found and regulatory and/or administrative sanctions by FDA are indicated.

Affordability and Fair Pricing

Description

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. 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.

Accounting Metrics

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.

.54 The registrant shall disclose all instances in which it entered into settlement relating to a challenge of one of its patents under the Paragraph IV-certified Abbreviated New Drug Application (ANDA) process established under the Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman Act") and in which that settlement involved compensation for the generic challenger and/or an agreement on behalf of the generic challenger to delay entry to the market of a generic bioequivalent.

.55 Payments include direct monetary settlement paid to a generic manufacturer as well as forms of implicit compensation, such as reduced royalty payment for delayed market entry or agreement by the registrant not to introduce its own authorized generic (AG) during the 180-day "first filer" period.

.56 The registrant should indicate if it entered multiple settlements for the same product.

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.

.57 The average net price increases should be weighted based on sales volume of all of the registrant's products sold in the U.S. during the fiscal year.

.58 The registrant should use the annual (December to December increase) of the Consumer Price Index for All Urban Consumer (CPI-U) for the fiscal year. Current Consumer Price Index data from the U.S. Department of Labor can be accessed here.

NOTES

HC0101-10

Additional References:
Pharmaceutical Agreement filings with the FTC under The Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

Ethical Marketing

Description

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.

Accounting Metrics

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.

.59 The registrant shall briefly describe the nature and context of fines and settlements related to promotion of off-label use of its products, including civil actions (e.g., civil judgment, settlements or regulatory penalties) and criminal actions (e.g., criminal judgment, penalties or restitutions) taken by any entity (government, businesses, or individuals).

.60 This includes whistleblower cases related to off-label marketing of the registrant's products in violation of the Federal Food, Drug, and Cosmetic Act prosecuted under the False Claims Act.

.61 The registrant shall disclose the amount of any fine or settlement associated with each incident, not including legal fees.

.62 The registrant shall describe any corrective actions it has implemented as a result of each incident. This may include, but is not limited to, specific changes in operations, management, processes, products, business partners, training, or technology.

.63 If relevant, the registrant should discuss other implications associated with the fine or settlement, such as exclusion from government reimbursement programs, entry into Corporate Integrity Agreements (CIAs) with governmental agencies and amendments to existing CIAs.

HC0101-13. Description of code of ethics governing promotion of off-label use of products, including mechanisms to ensure compliance.

.64 The registrant shall describe the aspects of its code of ethics that relate to ethical marketing and off-label promotion, including describing how it defines and/or what it considers "off-label promotion."

.65 A corporate policy, code of conduct, guideline, or contractual term that is similar in intent to a code of ethics shall be treated as equivalent for the purposes of this metric.

.66 The registrant shall describe the mechanisms it has in place to ensure compliance with its code, which may include training, internal audits, regulatory review committees, or disciplinary actions for violations.

NOTES

HC0101-13

Definitions

Promotion – any proactive activities (written, oral, or otherwise) that directly or indirectly market, sell, or support product sales and use, or that contribute to the sales growth of the registrant's products.

Off-label use – when a drug is used in a way that is different from that described in the FDA-approved drug label, it's said to be an "off-label" use. This can mean that the drug is: used for a different disease or medical condition, given in a different way (such as by a different route), or given in a different dose than in the approved label.

Employee Recruitment, Development, and Retention

Description

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.

Accounting Metrics

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.

.67 The registrant shall describe its strategy to attract and retain talent, including specific efforts related to mentorship programs, career development programs, and leadership training, as well as any incentive structures employed by the registrant that may be unique (such as team-based incentives). It may be relevant to describe the following elements of programs: overview, implementation, participation, effectiveness (with any quantitative metrics).

.68 Discussion shall focus on scientists and other personnel that are directly involved in research and development of activities for new biopharmaceutical products.

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.

.69 The registrant shall calculate (1) qualification and education expenditures per employee as: total dollar amount for the fiscal year spent on industry and professional qualification (such as credentialing programs and board certification) plus total dollar amount for the fiscal year spent on advanced industry education (such as degree and certificate programs directly related to job function) divided by full time employees (monthly average for fiscal year).

.70 The registrant shall calculate (2) all other training expenditures per employee as the absolute value of: total dollar amount spend on all employee job-related training less dollar amount spent on industry and professional qualification and advanced industry education (calculated above) divided by full time employees (monthly average for fiscal year).

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).

.71 The registrant shall classify all employees according to the U.S. Equal Employment Opportunity Commission EEO-1 Job Classification Guide and record the number of employees employed at any time during the fiscal year in each classification.

.72 For each classification, the registrant shall calculate monthly voluntary turnover as = total number of employee-initiated voluntary separations (such as resignation, retirement, etc.) for each month divided by the average number of employees for the month (the sum of the employees on the registrant's payroll at each pay period / number of pay periods). The registrant shall disclose its annual voluntary turnover rate which is calculated by adding the 12 monthly turnover figures together and multiplying by 100 to arrive at a percentage.

.73 For each classification the registrant shall calculate monthly involuntary turnover as = total number of registrant-initiated separation (such as dismissal, downsizing, redundancy, expiry of contract, etc.) for each month divided by the average number of employees for the month (the sum of the employees on the registrant's payroll at each pay period / number of pay periods). The registrant shall disclose its annual involuntary turnover rate, which is calculated by adding the 12 monthly turnover figures together and multiplying them by 100 to arrive at a percentage.

NOTES

HC0101-16

Additional References:
Society of Human Resources Management, Executive Brief: Tracking Trends in Employee Turnover

Employee Health and Safety

Description

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.

Accounting Metrics

HC0101-17. Total Injury Rate – (Number of recordable injuries and illnesses / Hours Worked)*200,000.

.74 If a registrant's workforce is entirely U.S.-based, it shall disclose its total injury rate as calculated and reported in the Occupational Safety and Health Administration's (OSHA) Form 300.

.75 If a registrant's workforce includes non-U.S.-based employees, it shall calculate its total injury rate according to the U.S. Bureau of Labor Statistics guidance and/or using the U.S. Bureau of Labor Statistics calculator.

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.

.76 If a registrant's workforce is entirely U.S.-based, it shall disclose its DART rate as calculated and reported in the Occupational Safety and Health Administration's (OSHA) Form 300.

.77 If a registrant's workforce includes non-U.S.-based employees, it shall calculate its DART rate according to the U.S. Bureau of Labor Statistics guidance and/or using the U.S. Bureau of Labor Statistics calculator.

HC0101-19. Laboratory-acquired infection (LAI) rate – LAIs per 1000 employees in human and animal diagnostic laboratories.

.78 Laboratory-acquired infections include all infections acquired through laboratory or laboratory-related activities, regardless whether they are symptomatic or asymptomatic in nature.

.79 The registrant shall disclose the number of laboratory-acquired infections per 1000 employees, even if these incidents are included in data for HC0101-17 and/or HC0101-18.

Counterfeit Drugs

Description

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 10–15 percent of the world's pharmaceuticals market. This issue presents a significant health and safety risk to consumers with an estimated 100,000 annual deaths attributed to substandard or counterfeit drugs worldwide. Biotechnology companies subsequently face material risks associated with the potential loss of public confidence and reduced revenue.

HC0101-20. Description of methods and technologies used to maintain traceability of products throughout the supply chain and prevent counterfeiting.

.80 Traceability refers to the ability to track identifying information (e.g., chemical composition, supplier, production date, production location, processing history, etc.) of a product throughout various stages of manufacturing and distribution (such as raw material source, manufacturing, distribution, and retail). For the biotechnology industry, relevant stages include manufacturing, logistics transportation, drug wholesale and distribution, and pharmacy retail.

.81 The registrant shall discuss the type and sophistication of technology it uses to maintain traceability and serialization of its products. This may range from the use of a barcode to the use of radio frequency identification (RFID) tagging.

HC0101-21. Description of process for alerting end customers and business partners of potential or known risks associated with counterfeit products.

.82 Business partners include suppliers, wholesalers, retailers, hospitals, etc.

.83 In addition to providing an overview of its procedures, the registrant shall describe how it communicates potential or known risks associated with the counterfeit products (e.g., through maintenance of a list of products with a higher risk of being counterfeited), recommended actions for the respective parties to minimize risks of counterfeiting, and mechanisms for product recall.

NOTES

HC0101-20

Additional References:
Prescription Drug Marketing Act pedigree requirements.

HC0101-22. Number (and description) of actions that led to raids, seizure, arrests, and/or filing of criminal charges related to counterfeit products.

.84 The registrant shall disclose the number of instances in which it took action to alert and/or aid regulatory authorities or law enforcement agencies with respect to counterfeiting. This may include having provided information or evidence that led to raids or arrests of counterfeiters or the seizure of counterfeit products, or instances where it the filed criminal charges against counterfeiters. If the registrant collaborated with other entities, such as manufacturers, wholesalers, or pharmacies, it may disclose these instances but should indicate which other entities were involved.

.85 The registrant shall also provide a description of actions taken, including – where relevant – the parties involved, role of the registrant, type and value of products in question, and outcome of the action.

.86 Relevant authorities and agencies include the U.S. FDA, the British Medicines and Healthcare products Regulatory Authority (MHRA), the Australian Therapeutic Goods Administration (TGA), or equivalent agencies.

Energy, Water, and Waste Efficiency

Description

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.

Accounting Metrics

HC0101-23. Total annual energy consumed (gigajoules) and percentage renewable (e.g., wind, biomass, solar).

.87 The registrant shall convert the amount of electricity it consumed from kilowatt hours (kWh) to gigajoules (GJ).

.88 The registrant shall disclose fossil fuel consumption in terms of its energy content, using higher heating values (HHV), also known as gross calorific values (GCV), and which are directly measured or taken from the Intergovernmental Panel on Climate Change (IPCC), the U.S. Department of Energy (DOE), or the U.S. Energy Information Administration (EIA).

.89 The registrant shall disclose renewable energy consumption as a percentage of its overall energy consumption, in terms of its energy content. For biofuels, the registrant shall use HHVs from the sources mentioned above. For solar or wind energy consumption, the registrant shall convert from electricity production (kWh) to gigajoules (GJ).

.90 The registrant shall disclose renewable energy data for renewable energy it directly produces, or which it purchases through renewable energy certificates (RECs) that are certified (i.e., through Green-e), or renewable power purchase agreements (PPAs). It shall not disclose the renewable portion of the energy drawn from electricity grids.

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.

.91 Water withdrawal is the total amount of water removed from freshwater sources for use in operations. This figure should not include water use in manufacturing that is recycled. Water withdrawals shall be disclosed in terms of cubic meters (m^3).

.92 Using the World Resources Institute's (WRI) Water Risk Atlas tool, Aqueduct (publicly available online here), the registrant shall analyze all of its manufacturing facilities for water risks and identify facilities that are in a location with High (40–80%) or Extremely High (>80%) Baseline Water Stress.

.93 The registrant shall separately disclose the percentage of total water withdrawals by volume (m^3) that was recycled during the fiscal year. This figure shall include the amount recycled in closed loop and open loop systems. Water recycled for purposes other than manufacturing processes (e.g., grey water reuse) shall not be included in this figure.

NOTES

HC0101-24

Additional References:
Corporate Water Disclosure Guidelines: Toward a Common Approach to Reporting Water Issues, CEO Water Mandate, August 2012.

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).

.94 PMI is as defined by the American Chemical Society (ACS) Green Chemistry Institute Pharmaceutical Roundtable. "Process" is defined as all steps of a synthetic path from commonly available materials to the final bulk active pharmaceutical ingredient (API). "Raw material input" is defined as all materials, including water, that are used directly in the process of synthesizing, isolating, and purifying the API salt. "Quantity of API output" is defined as the final salt form of the active ingredient that was produced in the synthesis, dried to the expected specification.

.95 The registrant should disclose total PMI for all raw material inputs, as well as separate PMI figures for water inputs and organic solvent inputs.

HC0101-26. Amount of waste (metric tons); percentage that is recycled, incinerated (including for energy recovery), and landfilled.

.96 The registrant shall calculate and disclose the total amount of waste that is recycled (or reused), incinerated, and landfilled. The registrant should specify other methods for disposition of waste (e.g., composting or permanent long-term storage).

.97 Waste includes hazardous and non-hazardous wastes. Hazardous waste includes EPA-listed wastes, characteristic wastes, universal wastes, and mixed wastes. The U.S. EPA provides a hazardous waste identification process.

.98 Waste shall be limited to that which is produced during the manufacturing process.

.99 Non-hazardous waste includes both municipal and solid waste.

NOTES

HC0101-25

Additional References: Using the Right Green Yardstick: Why Process Mass Intensity Is Used in the Pharmaceutical Industry To Drive More Sustainable Processes, Concepcion Jimenez-Gonzalez, Celia S. Ponder, Quirinus B. Broxterman, and Julie B. Manley Organic Process Research & Development 2011 15 (4), 912-917

HC0101-26

Additional References:
40 CFR – Title 40 – Protection of the Environment, Parts 239 – 282

Corruption and Bribery

Description

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.

Accounting Metrics

HC0101-27. Description of legal and regulatory fines and settlements associated with bribery, corruption, or other unethical business practices, including violations of the Foreign Corrupt Practices Act and those associated with providing kickbacks to physicians. Dollar amount of fines and settlements and a description of corrective actions implemented in response to events.

.100 The registrant shall briefly describe the nature and context of fines and settlements (e.g., non-prosecution agreement) associated with bribery, corruption, or other unethical business practices (e.g., indirect enticements such as kick-backs). These shall include civil actions (e.g., civil judgment, settlements, or regulatory penalties) and criminal actions (e.g., criminal judgment, penalties, or restitutions) taken by any entity (government, businesses, or individuals).

.101 Disclosure shall include violations of the Foreign Corrupt Practices Act related to its anti-bribery or accounting provisions and enforced by the Department of Justice or the Securities and Exchange Commission.

.102 The registrant shall disclose the amount of any fine or settlement associated with each incident, not including legal fees.

.103 The registrant shall describe any corrective actions it has implemented as a result of each incident. This may include, but is not limited to, specific changes in operations, management, processes, products, business partners, training, or technology.

HC0101-28. Description of code of ethics governing interactions with health care professionals including mechanisms to ensure employee compliance.

.104 The registrant shall describe aspects of any code of ethics that relate to the registrant's interactions with health care professions. Relevant aspects to discuss include the content (topics such as food and entertainment, training and education, and participation in committees that set formularies) and scope (type and percentage of staff to which it relates).

.105 "Health Care Professionals" includes individuals or entities which are involved in the provision of health care services and/or items to patients, such as physicians, dentists, pharmacists, and nurses. Additionally, the term includes those who purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe the registrant's products, but do not necessarily provide health care services directly, such as purchasing agents, practice managers, and group purchasing organizations (GPOs).

.106 A corporate policy, code of conduct, guidelines, or contractual term that is similar in intent to a code of ethics shall be treated as equivalent for the purposes of this metric.

.107 The registrant shall discuss mechanisms to ensure compliance with its code, such as training (including the degree and frequency) and enforcement (for example, inspections or review committees).

.108 If the registrant has adopted a second- or third-party code of ethics such as PhRMA's Code on Interactions with Healthcare Professionals, it may reference this code without describing the content.

Manufacturing and Supply Chain Quality Management

Description

Manufacturing and supply chain quality is 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.

Accounting Metrics

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.

.109 The registrant shall briefly describe the type (e.g., form 483, recall, Consent Decree, etc.), nature, and context of any FDA enforcement action taken during the fiscal year in response to current good manufacturing practice violations at its facilities.

.110 The registrant shall describe any corrective actions it has implemented as a result of each incident. This may include, but is not limited to, specific changes in operations, management, processes, products, business partners, training, or technology.

.111 Scope: Facilities discussed shall be those recognized by the registrant as physical assets under Property, Plant, and Equipment (Topic 360).

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.).

.112 The registrant shall disclose the percentage of its facilities that participate in the Rx-360 International Pharmaceutical Supply Chain Consortium audit program or equivalent third-party audit programs for integrity of supply chain and ingredients.

.113 The registrant shall disclose the percentage of its Tier I suppliers' facilities (limited to facilities with which the registrant conducts business) that participate in the Rx-360 (or equivalent) audit program.

- Tier I suppliers are those that transact directly with the registrant.
- The registrant may limit its disclosure to those suppliers that in aggregate account for greater than or equal to 90% of its supplier spending (in dollars).

.114 An equivalent third-party audit program is one conducted by an external auditing agency and that contains the same integrity of supply chain and integrity of ingredient requirements as the Rx-360 program.

.115 **Scope:** Facilities discussed shall be those recognized by the registrant as physical assets under Property, Plant, and Equipment (Topic 360).

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