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HEALTH CARE SECTOR

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# BIOTECHNOLOGY & PHARMACEUTICALS

## Sustainability Accounting Standard

Sustainable Industry Classification System® (SICS®) HC-BP

Prepared by the  
Sustainability Accounting Standards Board

October 2018

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# BIOTECHNOLOGY & PHARMACEUTICALS

## Sustainability Accounting Standard

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### About SASB

The SASB Foundation was founded in 2011 as a not-for-profit, independent standards-setting organization. The SASB Foundation's mission is to establish and maintain industry-specific standards that assist companies in disclosing financially material, decision-useful sustainability information to investors.

The SASB Foundation operates in a governance structure similar to the structure adopted by other internationally recognized bodies that set standards for disclosure to investors, including the Financial Accounting Standards Board (FASB) and the International Accounting Standards Board (IASB). This structure includes a board of directors ("the Foundation Board") and a standards-setting board ("the Standards Board" or "the SASB"). The Standards Board develops, issues, and maintains the SASB standards. The Foundation Board oversees the strategy, finances and operations of the entire organization, and appoints the members of the Standards Board.

The Foundation Board is not involved in setting standards, but is responsible for overseeing the Standards Board's compliance with the organization's due process requirements. As set out in the *SASB Rules of Procedure*, the SASB's standards-setting activities are transparent and follow careful due process, including extensive consultation with companies, investors, and relevant experts.

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## INTRODUCTION

### Purpose of SASB Standards

The SASB’s use of the term “sustainability” refers to corporate activities that maintain or enhance the ability of the company to create value over the long term. Sustainability accounting reflects the governance and management of a company’s environmental and social impacts arising from production of goods and services, as well as its governance and management of the environmental and social capitals necessary to create long-term value. The SASB also refers to sustainability as “ESG” (environmental, social, and governance), though traditional corporate governance issues such as board composition are not included within the scope of the SASB’s standards-setting activities.

SASB standards are designed to identify a minimum set of sustainability issues most likely to impact the operating performance or financial condition of the typical company in an industry, regardless of location. SASB standards are designed to enable communications on corporate performance on industry-level sustainability issues in a cost-effective and decision-useful manner using existing disclosure and reporting mechanisms.

Businesses can use the SASB standards to better identify, manage, and communicate to investors sustainability information that is financially material. Use of the standards can benefit businesses by improving transparency, risk management, and performance. SASB standards can help investors by encouraging reporting that is comparable, consistent, and financially material, thereby enabling investors to make better investment and voting decisions.

### Overview of SASB Standards

The SASB has developed a set of 77 industry-specific sustainability accounting standards (“SASB standards” or “industry standards”), categorized pursuant to SASB’s [Sustainable Industry Classification System® \(SICS®\)](#). Each SASB standard describes the industry that is the subject of the standard, including any assumptions about the predominant business model and industry segments that are included. SASB standards include:

1. **Disclosure topics** – A minimum set of industry-specific disclosure topics reasonably likely to constitute material information, and a brief description of how management or mismanagement of each topic may affect value creation.
2. **Accounting metrics** – A set of quantitative and/or qualitative accounting metrics intended to measure performance on each topic.
3. **Technical protocols** – Each accounting metric is accompanied by a technical protocol that provides guidance on definitions, scope, implementation, compilation, and presentation, all of which are intended to constitute suitable criteria for third-party assurance.
4. **Activity metrics** – A set of metrics that quantify the scale of a company’s business and are intended for use in conjunction with accounting metrics to normalize data and facilitate comparison.

Furthermore, the *SASB Standards Application Guidance* establishes guidance applicable to the use of all industry standards and is considered part of the standards. Unless otherwise specified in the technical protocols contained in the industry standards, the guidance in the SASB Standards Application Guidance applies to the definitions, scope, implementation, compilation, and presentation of the metrics in the industry standards.

The *SASB Conceptual Framework* sets out the basic concepts, principles, definitions, and objectives that guide the Standards Board in its approach to setting standards for sustainability accounting. The *SASB Rules of Procedure* is focused on the governance processes and practices for standards setting.

## Use of the Standards

SASB standards are intended for use in communications to investors regarding sustainability issues that are likely to impact corporate ability to create value over the long term. Use of SASB standards is voluntary. A company determines which standard(s) is relevant to the company, which disclosure topics are financially material to its business, and which associated metrics to report, taking relevant legal requirements into account<sup>1</sup>. In general, a company would use the SASB standard specific to its primary industry as identified in *SICS*<sup>®</sup>. However, companies with substantial business in multiple *SICS*<sup>®</sup> industries can consider reporting on these additional SASB industry standards.

It is up to a company to determine the means by which it reports SASB information to investors. One benefit of using SASB standards may be achieving regulatory compliance in some markets. Other investor communications using SASB information could be sustainability reports, integrated reports, websites, or annual reports to shareholders. There is no guarantee that SASB standards address all financially material sustainability risks or opportunities unique to a company's business model.

## Industry Description

The Biotechnology & Pharmaceuticals industry develops, manufactures, and markets a range of brand-name and generic medications. A significant portion of the industry is driven by research and development, a high risk of product failure during clinical trials, and the need to obtain regulatory approval. Concerns over pricing practices and consolidation within the sector have created downward pricing pressures. Demand for the industry's products is largely driving by population demographics, rates of insurance coverage, disease profiles, and economic conditions.

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<sup>1</sup> **Legal Note:** SASB standards are not intended to, and indeed cannot, replace any legal or regulatory requirements that may be applicable to a reporting entity's operations.

## SUSTAINABILITY DISCLOSURE TOPICS & ACCOUNTING METRICS

**Table 1. Sustainability Disclosure Topics & Accounting Metrics**

TOPIC	ACCOUNTING METRIC	CATEGORY	UNIT OF MEASURE	CODE
Safety of Clinical Trial Participants	Discussion, by world region, of management process for ensuring quality and patient safety during clinical trials	Discussion and Analysis	n/a	HC-BP-210a.1
	Number of FDA Sponsor Inspections related to clinical trial management and pharmacovigilance that resulted in: (1) Voluntary Action Indicated (VAI) and (2) Official Action Indicated (OAI)	Quantitative	Number	HC-BP-210a.2
	Total amount of monetary losses as a result of legal proceedings associated with clinical trials in developing countries <sup>2</sup>	Quantitative	Reporting currency	HC-BP-210a.3
Access to Medicines	Description of actions and initiatives to promote access to health care products for priority diseases and in priority countries as defined by the Access to Medicine Index	Discussion and Analysis	n/a	HC-BP-240a.1
	List of products on the WHO List of Prequalified Medicinal Products as part of its Prequalification of Medicines Programme (PQP)	Discussion and Analysis	n/a	HC-BP-240a.2
Affordability & Pricing	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	Quantitative	Number	HC-BP-240b.1
	Percentage change in: (1) average list price and (2) average net price across U.S. product portfolio compared to previous year	Quantitative	Percentage (%)	HC-BP-240b.2
	Percentage change in: (1) list price and (2) net price of product with largest increase compared to previous year	Quantitative	Percentage (%)	HC-BP-240b.3
Drug Safety	List of products listed in the Food and Drug Administration's (FDA) MedWatch Safety Alerts for Human Medical Products database	Discussion and Analysis	n/a	HC-BP-250a.1
	Number of fatalities associated with products as reported in the FDA Adverse Event Reporting System	Quantitative	Number	HC-BP-250a.2
	Number of recalls issued, total units recalled	Quantitative	Number	HC-BP-250a.3
	Total amount of product accepted for take-back, reuse, or disposal	Quantitative	Metric tons (t)	HC-BP-250a.4

<sup>2</sup> Note to **HC-BP-210a.3** – The entity shall briefly describe the nature, context, and any corrective actions taken as a result of the monetary losses.

TOPIC	ACCOUNTING METRIC	CATEGORY	UNIT OF MEASURE	CODE
	Number of FDA enforcement actions taken in response to violations of current Good Manufacturing Practices (cGMP), by type <sup>3</sup>	Quantitative	Number	HC-BP-250a.5
Counterfeit Drugs	Description of methods and technologies used to maintain traceability of products throughout the supply chain and prevent counterfeiting	Discussion and Analysis	n/a	HC-BP-260a.1
	Discussion of process for alerting customers and business partners of potential or known risks associated with counterfeit products	Discussion and Analysis	n/a	HC-BP-260a.2
	Number of actions that led to raids, seizure, arrests, and/or filing of criminal charges related to counterfeit products	Quantitative	Number	HC-BP-260a.3
Ethical Marketing	Total amount of monetary losses as a result of legal proceedings associated with false marketing claims <sup>4</sup>	Quantitative	Reporting currency	HC-BP-270a.1
	Description of code of ethics governing promotion of off-label use of products	Discussion and Analysis	n/a	HC-BP-270a.2
Employee Recruitment, Development & Retention	Discussion of talent recruitment and retention efforts for scientists and research and development personnel	Discussion and Analysis	n/a	HC-BP-330a.1
	(1) Voluntary and (2) involuntary turnover rate for: (a) executives/senior managers, (b) mid-level managers, (c) professionals, and (d) all others	Quantitative	Rate	HC-BP-330a.2
Supply Chain Management	Percentage of (1) entity's facilities and (2) Tier I suppliers' facilities 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	Quantitative	Percentage (%)	HC-BP-430a.1
Business Ethics	Total amount of monetary losses as a result of legal proceedings associated with corruption and bribery <sup>5</sup>	Quantitative	Reporting currency	HC-BP-510a.1
	Description of code of ethics governing interactions with health care professionals	Discussion and Analysis	n/a	HC-BP-510a.2

<sup>3</sup> Note to **HC-BP-250a.5** – The entity shall briefly describe the nature, context, and any corrective actions taken as a result of the enforcement actions.

<sup>4</sup> Note to **HC-BP-270a.1** – The entity shall briefly describe the nature, context, and any corrective actions taken as a result of the monetary losses.

<sup>5</sup> Note to **HC-BP-510a.1** – The entity shall briefly describe the nature, context, and any corrective actions taken as a result of the monetary losses.

**Table 2. Activity Metrics**

<b>ACTIVITY METRIC</b>	<b>CATEGORY</b>	<b>UNIT OF MEASURE</b>	<b>CODE</b>
Number of patients treated	Quantitative	Number	HC-BP-000.A
Number of drugs (1) in portfolio and (2) in research and development (Phases 1-3)	Quantitative	Number	HC-BP-000.B

# Safety of Clinical Trial Participants

## Topic Summary

Clinical trials are an essential component of the approval process for biotechnology and pharmaceutical products. The safety of clinical trial participants is a critical component of a company's ability to successfully bring a product to market. Oversight of these trials is an important factor in the industry due to the number of clinical trials conducted by third party contract research organizations as well as those conducted in emerging markets. Biotechnology and pharmaceuticals companies that effectively manage clinical trials may be positioned to enhance shareholder value through the revenue associated with new products.

## Accounting Metrics

### **HC-BP-210a.1. Discussion, by world region, of management process for ensuring quality and patient safety during clinical trials**

- 1 The entity shall describe its oversight of clinical research organizations' (CROs') quality and safety systems, such as the type of procedures followed, use and frequency of audits or inspections, and enforcement mechanisms.
  - 1.1 A clinical research organization or contract research organization (CRO) is a scientific organization (commercial, academic or other) to which the entity has transferred some of its tasks and obligations as a sponsor.
- 2 The entity shall discuss its management process for CROs, broken down by the following world regions: North America, Central and Latin America, Asia (including the Middle East), and Africa.
- 3 The entity may describe the nature and terms of monetary incentives that it uses or that are used by the CROs with which it contracts.
  - 3.1 Reimbursements for meal, travel, or lodging are excluded from the scope of the discussion.
- 4 The entity shall describe the process for obtaining informed consent from participants in clinical trials.
  - 4.1 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 entity:
    - 4.1.1 Disclosing to potential research subjects information needed to make an informed decision
    - 4.1.2 Facilitating the understanding of what has been disclosed
    - 4.1.3 Promoting the voluntariness of the decision about whether or not to participate in the research

- 5 The entity shall list all clinical trials, conducted by the entity (including those outsourced to third parties such as CROs), that were terminated for failure to follow good clinical practice (GCP) standards.
  - 5.1 Good Clinical Practice (GCP) standards are defined and regulated by the U.S. Food and Drug Administration and through international GCP guidance that has been adopted by the FDA.
- 6 The entity 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).
- 7 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, or lack of participants.
- 8 The scope of the disclosure includes the entity's management process with respect to all CROs it has worked with during the past reporting period or with which it has worked with in the past and plans to work with in the future.

### **HC-BP-210a.2. Number of FDA Sponsor Inspections related to clinical trial management and pharmacovigilance that resulted in: (1) Voluntary Action Indicated (VAI) and (2) Official Action Indicated (OAI)**

- 1 The entity shall disclose inspections of investigators that conducted clinical trials for the entity or on behalf of the entity (such as at a clinical research organization (CRO)).
- 2 The entity shall disclose the number of inspections related to its own clinical trials that resulted in a classification of Voluntary Action Indicated (VAI) or Official Action Indicated (OAI).
  - 2.1 The entity may access the publicly available [Clinical Investigator Inspection Search](#).
  - 2.2 The entity may search the database for inspections of investigators that they have used for clinical trials during the reporting period. The FDA's Clinical Investigator Inspection List (CLIL) 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 entity's facilities or clinical research organizations (CROs) it uses.
  - 2.3 The results of the inspection are listed in the "Classification" column.

### **HC-BP-210a.3. Total amount of monetary losses as a result of legal proceedings associated with clinical trials in developing countries**

- 1 The entity shall disclose the total amount of monetary losses it incurred during the reporting period as a result of legal proceedings associated with clinical trials in developing countries.

- 1.1 The scope of the disclosure shall include, but is not limited to, legal proceedings associated with clinical trials in countries that meet the criteria established by the most recent Access to Medicine Index Methodology, including:
  - 1.1.1 Low-income as defined by the World Bank income classifications
  - 1.1.2 Lower-middle-income as defined by the World Bank income classifications
  - 1.1.3 Least developed country as defined by the UN Committee for Development Policy
  - 1.1.4 Low or medium human development country as defined by the UN Human Development Index
  - 1.1.5 All countries that receive a score of less than 0.6 on the UN Inequality-Adjusted Human Development Index
  - 1.1.6 All least developed countries as defined by the United Nations Economic and Social Council (ECOSOC)
- 2 The legal proceedings shall include any adjudicative proceeding in which the entity was involved, whether before a court, a regulator, an arbitrator, or otherwise.
- 3 The losses shall include all monetary liabilities to the opposing party or to others (whether as the result of settlement or verdict after trial or otherwise), including fines and other monetary liabilities incurred during the reporting period as a result of civil actions (e.g., civil judgments or settlements), regulatory proceedings (e.g., penalties, disgorgement, or restitution), and criminal actions (e.g., criminal judgment, penalties, or restitution) brought by any entity (e.g., governmental, business, or individual).
- 4 The scope of monetary losses shall exclude legal and other fees and expenses incurred by the entity in its defense.
- 5 The scope of disclosure shall include, but is not limited to, legal proceedings associated with the enforcement of relevant industry regulations promulgated by regional, federal, state, and local regulatory authorities, such as the U.S. Food and Drug Administration (FDA).

Note to **HC-BP-210a.3**

- 1 The entity shall briefly describe the nature (e.g., judgment or order issued after trial, settlement, guilty plea, deferred prosecution agreement, or non-prosecution agreement) and context (e.g., failure to obtain informed consent or failure to port ethical review of the protocol) of all monetary losses as a result of legal proceedings.
- 2 The entity shall describe any corrective actions it has implemented as a result of the legal proceedings. This may include, but is not limited to, specific changes in operations, management, processes, products, business partners, training, or technology.

# Access to Medicines

## Topic Summary

Biotechnology and pharmaceuticals 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. Strategic approaches related to access to medicines can yield opportunities for growth, innovation, and unique partnerships, which may enhance shareholder value.

## Accounting Metrics

### **HC-BP-240a.1. Description of actions and initiatives to promote access to health care products for priority diseases and in priority countries as defined by the Access to Medicine Index**

- 1 The entity shall disclose initiatives launched, funded, supported, or otherwise participated in during the reporting period that related to improving access to health care products for priority diseases and in priority countries.
- 2 The entity shall discuss products authorized for sale and available during the reporting period.
- 3 The entity shall discuss initiatives if implementation was ongoing during the reporting period. Initiatives that began or concluded during the reporting period may be discussed; the entity, however, should indicate this condition.
- 4 The entity may describe the following issues as they relate to access to health care initiatives:
  - 4.1 Research and development
  - 4.2 Pricing
  - 4.3 Public policy and market influence efforts
  - 4.4 Manufacturing and distribution
  - 4.5 Patents and licensing
  - 4.6 Product donations
  - 4.7 Philanthropic activities
- 5 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 World Health Organization (WHO) data. These include

communicable diseases, non-communicable diseases, neglected tropical diseases, maternal and neonatal health conditions, and priority pathogens. A full list is included in the most recent Access to Medicine Index Methodology.

- 6 Disclosure shall focus on initiatives related to the aforementioned diseases, conditions, and pathogens.
- 7 The entity may discuss additional or alternative diseases, conditions, and pathogens but should provide evidence that they are considered a priority in the priority countries discussed.
  - 7.1 Priority countries comprise those that are defined and identified in the most recent Access to Medicine Index Methodology.

### **HC-BP-240a.2. List of products on the WHO List of Prequalified Medicinal Products as part of its Prequalification of Medicines Programme (PQP)**

- 1 The entity shall disclose a list of its products authorized for sale and available during the reporting period that are on the World Health Organization (WHO) [List of Prequalified Medicinal Products](#).
  - 1.1 Multiple listings of the same active pharmaceutical ingredient (API) in different strengths (e.g., 30 mg and 20 mg) or in different formulations (e.g., tablet and capsule) shall be counted once.
  - 1.2 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 follow guidance for multiple strengths and formulations.
  - 1.3 Products listed under the status "Suspended" shall not be counted.
- 2 The list of products should be provided by International Nonproprietary Name (INN), including brand name(s) in parentheses where applicable.
- 3 The entity may disclose the number of its products targeting each WHO-defined therapeutic area, including, but not limited to:
  - 3.1 Diarrhea
  - 3.2 HIV/AIDS
  - 3.3 Influenza
  - 3.4 Malaria
  - 3.5 Reproductive health
- 4 Initiatives involving products targeting WHO-defined therapeutic areas shall be discussed if implementation was ongoing during the reporting period.

# Affordability & Pricing

## Topic Summary

Stakeholder emphasis on health care cost containment and increased access will likely continue to place downward pricing pressures on the Biotechnology & Pharmaceuticals industry. As a result, companies that have relied on raising drug prices, contractual advantages, and reverse payments to protect profits may be challenged to enhance value by efforts to reduce costs. Firms that prevent stakeholder scrutiny of pricing practices may limit their exposure to issues such as regulatory action, or adverse reputational impacts.

## Accounting Metrics

### **HC-BP-240b.1. 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**

- 1 The entity 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.
- 2 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 entity not to introduce its own authorized generic (AG) during the 180-day “first filer” period.
- 3 The entity should indicate if it entered multiple settlements for the same product.

### **HC-BP-240b.2. Percentage change in: (1) average list price and (2) average net price across U.S. product portfolio compared to previous year**

- 1 The entity shall disclose the average list price increase across all the entity’s pharmaceutical products sold in the U.S. during the reporting period, where:
  - 1.1 The annual average list price increase shall be calculated as percent change versus the prior year for each product weighted by list price across the entity’s U.S. portfolio of pharmaceutical products.
  - 1.2 The list price shall represent the average wholesale acquisition cost (WAC) and shall represent the average WAC for the year in which it is being calculated.

- 2 The entity shall disclose the average net price increase across all the entity's pharmaceutical products sold in the U.S. during the reporting period, where:
  - 2.1 The annual average net price increase shall be calculated as percent change versus the prior year and for each product weighted by list price across the entity's U.S. portfolio of pharmaceutical products.
  - 2.2 The net price shall represent the average wholesale acquisition cost (WAC) minus rebates, discounts, and returns and shall represent the average WAC minus rebates, discounts, and returns for the year in which it is being calculated.

### **HC-BP-240b.3. Percentage change in: (1) list price and (2) net price of product with largest increase compared to previous year**

- 1 The entity shall disclose the percent change in list price and the name of the product with the largest increase in list price compared to previous year, where:
  - 1.1 The change in net price increase shall be calculated as the percent change in price between the current and prior year for an individual product.
  - 1.2 List price should represent the average wholesale acquisition cost (WAC) for the specific product and shall represent the average WAC for the year in which it is being calculated.
- 2 The entity shall disclose the percent change in net price and the name of the product with the largest increase in net price compared to previous year, where:
  - 2.1 The change in net price increase should be calculated as percent change in price between the current and prior year for an individual product.
  - 2.2 The net price shall represent the average wholesale acquisition cost (WAC) minus rebates, discounts, and returns for the specific product and shall represent the average WAC minus rebates, discounts, and returns for the year in which it is being calculated.

# Drug Safety

## Topic Summary

Information on product safety can surface after controlled clinical trials and regulatory approval. Subsequently, companies are exposed to the financial implications of recalls and other adverse events. Product safety concerns, manufacturing defects, or inadequate disclosure of product-related risks can lead to significant product liability claims. Biotechnology and pharmaceuticals firms that limit the incidence of recalls, safety concerns, and enforcement actions for manufacturing concerns may 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 may limit future liabilities.

## Accounting Metrics

### HC-BP-250a.1. List of products listed in the Food and Drug Administration's (FDA) MedWatch Safety Alerts for Human Medical Products database

- 1 The entity shall disclose all drugs and therapeutic biological products associated with the entity that are listed in the Food and Drug Administration's (FDA) MedWatch Safety Alerts for Human Medical Products database.
  - 1.1 The entity may access the list through 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](#).
  - 1.2 The safety alerts are organized into four categories:
    - 1.2.1 Drugs and Therapeutic Biological Products
    - 1.2.2 Medical Devices
    - 1.2.3 Special Nutritional and Cosmetic Products
    - 1.2.4 Products with Undeclared Drug Ingredients
  - 1.3 The entity shall disclose all listings associated with the entity that appear in the Drugs and Therapeutic Biological Products list, including trade names for which the entity has patents or active ingredients or classes of product that it manufactures and markets.
- 2 The entity shall disclose all drugs and therapeutic biological products associated with the entity 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.

- 2.1 A list of products is available in 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).
  - 2.2 The entity shall disclose all listings associated with the entity that appear in the list, including trade names for which the entity has patents or active ingredients or classes of product that it manufactures and markets.
- 3 If the entity manufactures a product with an active ingredient or a product in a product class listed in these databases but has evidence that the listing does not apply to its specific products, it shall provide such evidence.

### **HC-BP-250a.2. Number of fatalities associated with products as reported in the FDA Adverse Event Reporting System**

- 1 The entity shall disclose the number of fatalities associated with all drugs and biologic products it manufactures.
- 2 The scope of the disclosure shall include all fatalities that occurred during the reporting period for which it is disclosing, even if the adverse event began in a prior period.
- 3 The entity may access a list of fatalities through the [FDA Adverse Event Reporting System \(FAERS\)](#).

### **HC-BP-250a.3. Number of recalls issued, total units recalled**

- 1 The entity shall disclose the total number of recalls for drug products that the entity manufactures, where:
  - 1.1 Recalls are defined as actions taken by an entity to remove a product from the market, including those conducted on the entity's own initiative, by the U.S. Food and Drug Administration (FDA) request, or by FDA order under statutory authority.
  - 1.2 Drugs are defined by the Federal Food, Drug, and Cosmetic (FD&C) Act sec. 201(g)(1) as articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and articles (other than food) intended to affect the structure or any function of the body of man or other animals.
  - 1.3 Drugs include:
    - 1.3.1 Pharmaceutical prescription products as well as over-the-counter medications
    - 1.3.2 Biological products
  - 1.4 The scope of disclosure shall include recalls associated with all devices manufactured by the entity or by its subsidiaries.
- 2 The entity shall identify all products manufactured by it or its subsidiaries for which it is listed as the recalling firm in the “Biologics” and “Drugs” product types in Food and Drug Administration (FDA) enforcement reports.

- 2.1 Entities may 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. These reports contain all recalls by product type, product description, code info, classification, reason for recall, and recalling firm.
- 3 The entity shall disclose recalls in non-U.S. markets that have been initiated voluntarily, at the request of a non-U.S. national regulatory authority, or by order of a non-U.S. national regulatory authority under statutory authority.
- 4 The entity shall 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.
- 5 The entity shall disclose the total number of drug units that were subject to a recall.
- 6 The entity shall disclose, in addition to the total number of drug recalls, the percentage of recalls that were:
  - 6.1 Voluntary
  - 6.2 FDA requested
  - 6.3 FDA mandated
- 7 For FDA-initiated recalls, the entity may disclose the FDA classification of each recall, including:
  - 7.1 Class I
  - 7.2 Class II
  - 7.3 Class III
- 8 For each recalled product, the entity may disclose revenues from 12 months prior to the date of recall. This 12-month period may extend beyond the reporting period for which the entity is disclosing; the figure is intended to indicate annual revenues associated with the product such that the financial impact of the recall can be gauged.
- 9 If a recall relates to only a subset of a product (e.g., specific lots or a particular style), then the entity should indicate the scope of the recall; and, if the entity is disclosing revenue associated with the recall, it should be limited to the portion of the product affected by the recall.
- 10 The entity shall discuss notable recalls such as those that affected a significant number of units of one product or those related to serious injury or fatality. For such recalls the entity should provide:
  - 10.1 Description and cause of the recall issue
  - 10.2 The total number of units recalled

- 10.3 The cost to remedy the issue
- 10.4 Whether the recall was initiated voluntarily or at the request of the FDA or non-U.S. national regulatory authority
- 10.5 Corrective actions
- 10.6 Any other significant outcomes (e.g., legal proceedings or customer fatalities)

#### **HC-BP-250a.4. Total amount of product accepted for take-back, reuse, or disposal**

- 1 The entity shall disclose the amount of unused product, in metric tons, that is accepted through take-back initiatives.
  - 1.1 Unused product includes that which is expired, unwanted, waste, or excess.
  - 1.2 Product take-back includes reclaiming unused products from end-consumers or medical facilities for redistribution or disposal.
  - 1.3 Biopharmaceutical reuse programs include redistribution initiatives aimed at providing medication to underserved populations, subject to state or local laws.
  - 1.4 Disposal of biopharmaceutical products includes, but is not limited to, high-temperature incineration that 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).
- 2 For initiatives that are co-funded by the entity, it shall prorate the amount of product accepted for take-back by its percentage contribution to the funding of the initiative.
- 3 The entity shall discuss systemic efforts related to end-of-life management of its products, including, but not limited to those intended to prevent:
  - 3.1 Back-market sales
  - 3.2 Abuse
  - 3.3 Release into the environment
- 4 The entity may disclose expenditures for funding of programs or initiatives that are financially supported and administered by the entity as well as initiatives funded by the entity that are administered by third parties for the express purpose of product take-back.

## **HC-BP-250a.5. Number of FDA enforcement actions taken in response to violations of current Good Manufacturing Practices (cGMP), by type**

1 The entity shall disclose the number and type of Food and Drug Administration (FDA) enforcement actions taken during the reporting period in response to current good manufacturing practice (cGMP) (or regional equivalent) violations at its facilities. Enforcement actions include, but are not limited to:

1.1 Form 483s

1.2 Warning letters

1.3 Seizures

1.4 Recalls

1.5 Consent decrees

2 The scope of disclosure includes facilities that are owned or operated by the entity.

### Note to **HC-BP-250a.5**

1 The entity shall describe the nature and context of the enforcement actions.

2 The entity 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.

# Counterfeit Drugs

## Topic Summary

The World Health Organization estimates that counterfeit drugs represent more than 10 percent of the pharmaceutical supply chain in low and middle-income countries. The issue of fake or substandard medication also presents a significant risk in developed economies. Biotechnology and pharmaceuticals companies may face added costs as numerous governments and agencies have implemented drug supply chain regulations in an effort to prevent counterfeit, substandard, or mislabeled drugs from entering the pharmaceutical distribution system. Companies that fail to manage this issue effectively may face material risks associated with the potential loss of public confidence and reduced revenue.

## Accounting Metrics

### **HC-BP-260a.1. Description of methods and technologies used to maintain traceability of products throughout the supply chain and prevent counterfeiting**

- 1 The entity shall discuss the type and sophistication of technology it uses to maintain traceability and serialization, as well as to prevent counterfeiting of its products, including, but not limited to, the use of barcode technology and radio frequency identification (RFID) tagging, where:
  - 1.1 Counterfeit drugs are defined as drugs sold under a product name without proper authorization. Counterfeiting can apply to both brand name and generic products, where the identity of the source is mislabeled in a way that suggests that it is the authentic, approved product. Counterfeit products may include products that lack the active ingredient, contain an insufficient or excessive quantity of the active ingredient, contain the wrong active ingredient, or have fake packaging.
  - 1.2 Traceability refers to the ability to track identifying information (e.g., chemical composition, supplier, production date, production location, or processing history) of a product throughout various stages of manufacturing and distribution (such as raw material sourcing, manufacturing, distribution, and retail).
- 2 Relevant elements of the product supply chain include, but are not limited to:
  - 2.1 Drug wholesale and distribution
  - 2.2 Manufacturing
  - 2.3 Pharmacy retail
  - 2.4 Transportation logistics

## **HC-BP-260a.2. Discussion of process for alerting customers and business partners of potential or known risks associated with counterfeit products**

- 1 The entity shall discuss its process for alerting customers and business partners of potential or known risks associated with counterfeit products.
  - 1.1 Customers include, but are not limited to, patients and physicians
  - 1.2 Business partners include, but are not limited to, suppliers, wholesalers, retailers, and hospitals
  - 1.3 Counterfeit drugs are defined as drugs sold under a product name without proper authorization. Counterfeiting can apply to both brand name and generic products, where the identity of the source is mislabeled in a way that suggests that it is the authentic, approved product. Counterfeit products may include products that lack the active ingredient, contain an insufficient or excessive quantity of the active ingredient, contain the wrong active ingredient, or have fake packaging
- 2 The scope of the disclosure shall include recommended actions for the respective parties to minimize risks of counterfeiting.
- 3 The scope of the disclosure shall include a description of the entity's mechanisms for product recall.

## **HC-BP-260a.3. Number of actions that led to raids, seizure, arrests, and/or filing of criminal charges related to counterfeit products**

- 1 The entity 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, including, but not limited to:
  - 1.1 The provision of information or evidence that led to raids or arrests of counterfeiters or the seizure of counterfeit products
  - 1.2 The filing of criminal charges against counterfeiters
- 2 Relevant authorities and agencies include, but are not limited to:
  - 2.1 The U.S. Food and Drug Administration (FDA)
  - 2.2 The British Medicines and Healthcare Products Regulatory Authority (MHRA)
  - 2.3 The Australian Therapeutic Goods Administration (TGA)
- 3 If the entity collaborated with other entities, such as manufacturers, wholesalers, or pharmacies, it may disclose these instances but should indicate which other entities were involved.

- 4 The entity shall also provide a description of actions taken, including—where relevant—the parties involved, role of the entity, type and value of products in question, and outcome of the action.

# Ethical Marketing

## Topic Summary

Biotechnology and pharmaceuticals companies face challenges associated with the marketing of specific products. Direct-to-consumer advertisements for prescription drugs provide opportunities for increasing market share. However, challenges arise from the potential for marketing off-label uses, which can result in significant fines and settlements. Corporate disclosure of legal and regulatory fines and the codes of ethics that govern marketing activities will allow shareholders to better understand performance in this area.

## Accounting Metrics

### **HC-BP-270a.1. Total amount of monetary losses as a result of legal proceedings associated with false marketing claims**

- 1 The entity shall disclose the total amount of monetary losses it incurred during the reporting period as a result of legal proceedings associated with false marketing claims.
- 2 The legal proceedings shall include any adjudicative proceeding in which the entity was involved, whether before a court, a regulator, an arbitrator, or otherwise.
- 3 The losses shall include all monetary liabilities to the opposing party or to others (whether as the result of settlement or verdict after trial or otherwise), including fines and other monetary liabilities as a result of civil actions (e.g., civil judgments or settlements), regulatory proceedings (e.g., penalties, disgorgement, or restitution), and criminal actions (e.g., criminal judgment, penalties, or restitution) brought by any entity (e.g., governmental, business, or individual).
- 4 The scope of monetary losses shall exclude legal and other fees and expenses incurred by the entity in its defense.
- 5 The scope of disclosure shall include, but is not limited to, legal proceedings associated with the enforcement of relevant industry regulations, such as the U.S. False Claims Act.

#### Note to **HC-BP-270a.1**

- 1 The entity shall briefly describe the nature (e.g., judgment or order issued after trial, settlement, guilty plea, deferred prosecution agreement, or non-prosecution agreement) and context (e.g., off-label promotion) of all monetary losses as a result of legal proceedings.
- 2 The entity shall describe any corrective actions it has implemented as a result of the legal proceedings. This may include, but is not limited to, specific changes in operations, management, processes, products, business partners, training, or technology.

## **HC-BP-270a.2. Description of code of ethics governing promotion of off-label use of products**

- 1 The entity 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."
- 2 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.
- 3 The entity shall describe the mechanisms it has in place to ensure compliance with its code, including, but not limited to:
  - 3.1 Disciplinary actions for violations
  - 3.2 Training
  - 3.3 Internal audits
  - 3.4 Regulatory review committees
  - 3.5 Training

# Employee Recruitment, Development & Retention

## Topic Summary

Biotechnology and pharmaceuticals 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 constrained talent pool may be better positioned to protect and enhance shareholder value.

## Accounting Metrics

### **HC-BP-330a.1. Discussion of talent recruitment and retention efforts for scientists and research and development personnel**

- 1 The entity shall describe its strategy to attract and retain talent, including, but not limited to:
  - 1.1 Mentorship programs
  - 1.2 Career development programs
  - 1.3 Leadership training
  - 1.4 Incentive structures
- 2 The entity may describe the following elements of recruitment and retention programs, including associated quantitative metrics:
  - 2.1 Overview
  - 2.2 Implementation
  - 2.3 Participation
  - 2.4 Effectiveness
- 3 The scope of the disclosure shall focus on scientists and other personnel that are directly involved in research and development of activities for new biopharmaceutical products.

**HC-BP-330a.2. (1) Voluntary and (2) involuntary turnover rate for: (a) executives/senior managers, (b) mid-level managers, (c) professionals, and (d) all others**

- 1 The entity shall disclose voluntary and involuntary employee turnover for all employees by the following employee categories:
  - 1.1 Executives/senior managers
  - 1.2 Mid-level managers
  - 1.3 Professionals
  - 1.4 All others
- 2 The entity 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 reporting period in each classification.
- 3 For each category of employee, the entity shall calculate monthly voluntary turnover.
  - 3.1 Voluntary turnover shall be calculated as the total number of employee-initiated, voluntary separation (such as resignation or retirement) for each month divided by the average number of employees for the month (the sum of the employees on the entity's payroll at each pay period / number of pay periods).
  - 3.2 The entity shall disclose its annual voluntary turnover rate, calculated by adding the 12 monthly turnover figures together and multiplying by 100 to arrive at a percentage.
- 4 For each category of employee, the entity shall calculate monthly involuntary turnover.
  - 4.1 Involuntary turnover shall be calculated as total number of entity-initiated separation (such as dismissal, downsizing, redundancy, or expiry of contract) for each month divided by the average number of employees for the month (the sum of the employees on the entity's payroll at each pay period / number of pay periods).
  - 4.2 The entity shall disclose its annual involuntary turnover rate which is calculated by adding the 12 monthly turnover figures together and multiplying by 100 to arrive at a percentage.

# Supply Chain Management

## Topic Summary

For the Biotechnology & Pharmaceuticals industry, supply chain quality is essential to protecting consumer health and corporate value. Biotechnology and pharmaceuticals firms that fail to ensure quality throughout their supply chains are susceptible to lost revenue, supply disruptions, and reputational damage. Disclosure of supply chain audit programs may provide shareholders with an understanding of how companies in this industry are protecting shareholder value.

## Accounting Metrics

### **HC-BP-430a.1. Percentage of (1) entity's facilities and (2) Tier I suppliers' facilities 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**

- 1 The entity shall disclose (1) 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.
  - 1.1 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.
  - 1.2 The scope of disclosure includes facilities that are owned or operated by the entity.
- 2 The entity shall disclose (2) the percentage of its Tier I suppliers' facilities (limited to facilities with which the entity conducts business) that participate in the Rx-360 (or equivalent) audit program.
  - 2.1 Tier I suppliers are those that transact directly with the entity.
  - 2.2 The entity may limit its disclosure to those suppliers that in aggregate account for greater than or equal to 90 percent of its supplier spending.

# Business Ethics

## Topic Summary

Biotechnology and pharmaceuticals firms are subject to various international, national, and state laws pertaining to health care fraud and abuse. For example, in the U.S., anti-kickback laws and the 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 throughout their global and domestic operational footprint may have material implications. Corporate disclosure of legal and regulatory fines and the codes of ethics that govern interactions with health professionals may allow shareholders to monitor performance in this area.

## Accounting Metrics

### **HC-BP-510a.1. Total amount of monetary losses as a result of legal proceedings associated with corruption and bribery**

- 1 The entity shall disclose the total amount of monetary losses it incurred during the reporting period as a result of legal proceedings associated with bribery and corruption.
- 2 The legal proceedings shall include any adjudicative proceeding in which the entity was involved, whether before a court, a regulator, an arbitrator, or otherwise.
- 3 The losses shall include all monetary liabilities to the opposing party or to others (whether as the result of settlement or verdict after trial or otherwise), including fines and other monetary liabilities incurred during the reporting period as a result of civil actions (e.g., civil judgments or settlements), regulatory proceedings (e.g., penalties, disgorgement, or restitution), and criminal actions (e.g., criminal judgment, penalties, or restitution) brought by any entity (e.g., governmental, business, or individual).
- 4 The scope of monetary losses shall exclude legal and other fees and expenses incurred by the entity in its defense.
- 5 The scope of disclosure shall include, but is not limited to, legal proceedings associated with the enforcement of relevant industry regulations, such as:
  - 5.1 The U.S. Federal Anti-Kickback Statute
  - 5.2 The U.S. Foreign Corrupt Practices Act
  - 5.3 The U.S. Federal Food, Drug, and Cosmetic Act

Note to **HC-BP-510a.1**

- 1 The entity shall briefly describe the nature (e.g., judgment or order issued after trial, settlement, guilty plea, deferred prosecution agreement, or non-prosecution agreement) and context (e.g., kickbacks or fraud) of all monetary losses as a result of legal proceedings.
- 2 The entity shall describe any corrective actions it has implemented as a result of the legal proceedings. This may include, but is not limited to, specific changes in operations, management, processes, products, business partners, training, or technology.

## **HC-BP-510a.2. Description of code of ethics governing interactions with health care professionals**

- 1 The entity shall describe aspects of any code of ethics that relate to the entity's interactions with health care professions.
  - 1.1 Health care professionals include 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 entity's products, but do not necessarily provide health care services directly, such as purchasing agents, practice managers, and group purchasing organizations (GPOs).
  - 1.2 The scope of the disclosure includes 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) of the code of ethics.
- 2 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.
- 3 The entity shall discuss mechanisms to ensure compliance with its code, such as training (including the degree and frequency) and enforcement (e.g., inspections or review committees).
  - 3.1 Enforcement, including inspection, compliance, and review committees
  - 3.2 Implementation of corrective actions when a code is violated
  - 3.3 Training, including degree and frequency
- 4 If the entity 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.

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