SASB STANDARDS

Now part of IFRS Foundation

Biotechnology & Pharmaceuticals

Sustainability Accounting Standard

HEALTH CARE SECTOR

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

Under Stewardship of the International Sustainability Standards Board

INDUSTRY STANDARD | VERSION 2023-12

IFRS® Sustainability

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About the SASB Standards

As of August 2022, the International Sustainability Standards Board (ISSB) of the IFRS Foundation assumed responsibility for the SASB Standards. The ISSB has committed to maintain, enhance and evolve the SASB Standards and encourages preparers and investors to continue to use the SASB Standards.

IFRS S1 *General Requirements for Disclosure of Sustainability-related Financial Information* (IFRS S1) requires entities to refer to and consider the applicability of disclosure topics in the SASB Standards when identifying sustainability-related risks and opportunities that could reasonably be expected to affect an entity's prospects. Similarly, IFRS S1 requires entities to refer to and consider the applicability of metrics in the SASB Standards when determining what information to disclose regarding sustainability-related risks and opportunities.

In June 2023, the ISSB amended climate-related topics and metrics in the SASB Standards to align them with the industry-based guidance accompanying IFRS S2 *Climate-related Disclosures*. In December 2023, the ISSB amended the non-climate-related topics and metrics in connection with the International Applicability of SASB Standards project.

Effective Date

This version 2023-12 of the Standard is effective for all entities for annual periods beginning or after January 1, 2025. Early adoption is permitted for all entities.

Table of Contents

INTRODUCTION

Overview of SASB Standards

The SASB Standards are a set of 77 industry-specific sustainability accounting standards ("SASB Standards" or "Industry Standards"), categorised pursuant to the Sustainable Industry Classification System® (SICS®).

SASB Standards include:

1. **Industry descriptions** – which are intended to help entities identify applicable industry guidance by describing the business models, associated activities and other common features that characterise participation in the industry.

2. **Disclosure topics** – which describe specific sustainability-related risks or opportunities associated with the activities conducted by entities within a particular industry.

3. **Metrics** – which accompany disclosure topics and are designed to, either individually or as part of a set, provide useful information regarding an entity's performance for a specific disclosure topic.

4. **Technical protocols** – which provide guidance on definitions, scope, implementation and presentation of associated metrics.

5. **Activity metrics** – which quantify the scale of specific activities or operations by an entity and are intended for use in conjunction with the metrics referred to in point 3 to normalise data and facilitate comparison.

Entities using the SASB Standards as part of their implementation of ISSB Standards should consider the relevant ISSB application guidance.

For entities using the SASB Standards independently from ISSB Standards, 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.

Historically, the *SASB Conceptual Framework* set out the basic concepts, principles, definitions and objectives that guided the SASB Standards Board in its approach to setting standards for sustainability accounting.

Use of the Standards

SASB Standards are intended to aid entities in disclosing information about sustainability-related risks and opportunities that could reasonably be expected to affect the entity's cash flows, its access to finance or cost of capital over the short, medium or long term. An entity determines which Industry Standard(s) and which disclosure topics are relevant to its business, and which associated metrics to report. In general, an entity should use the SASB Standard specific to its primary industry as identified in SICS® . However, companies with substantial business in multiple SICS® industries should refer to and consider the applicability of the disclosure topics and associated metrics in additional SASB Standards.

The disclosure topics and associated metrics contained in this Standard have been identified as those that are likely to be useful to investors. However, the responsibility for making materiality judgements and determinations rests with the reporting entity.

Industry Description

The Biotechnology & Pharmaceuticals industry develops, manufactures and markets a range of brand-name and generic medications. Research and development propels a significant portion of the industry and involves a high risk of product failure during clinical trials and the need to obtain regulatory approval. Concerns regarding sector pricing practices and consolidation have created downward pricing pressures. Primarily, demographics, insurance coverage rates, disease profiles and economic conditions drive consumer demand for the industry's products.

SUSTAINABILITY DISCLOSURE TOPICS & METRICS

Table 1. Sustainability Disclosure Topics & Metrics

TOPIC	METRIC	CATEGORY	UNIT OF MEASURE	CODE
Safety of Clinical Trial Participants	Discussion, by region, of management process for ensuring quality and patient safety during clinical trials	Discussion and Analysis	n/a	HC-BP-210a.1
	Number of inspections related to clinical trial management and pharmacovigilance that resulted in: (1) entity voluntary remediation or (2) regulatory or administrative actions taken against the entity	Quantitative	Number	HC-BP-210a.2
	Total amount of monetary losses as a result of legal proceedings associated with clinical trials in developing countries [1]	Quantitative	Presentation 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	Percentage change in: (1) weighted average list price and (2) weighted average net price across product portfolio compared to previous reporting period	Quantitative	Percentage (%)	HC-BP-240b.2
	Percentage change in: (1) list price and (2) net price of product with largest increase compared to previous reporting period	Quantitative	Percentage (%)	HC-BP-240b.3

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[1] Note to **HC-BP-210a.3** – The entity shall briefly describe the nature, context and any corrective actions taken because of monetary losses.

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TOPIC	METRIC	CATEGORY	UNIT OF MEASURE	CODE
Drug Safety	Products listed in public medical product safety or adverse event alert databases	Discussion and Analysis	n/a	HC-BP-250a.1
	Number of fatalities associated with products	Quantitative	Number	HC-BP-250a.2
	(1) Number of recalls issued, (2) total units recalled	Quantitative	Number	HC-BP-250a.3
	Total amount of product accepted for take-back, reuse, or disposal	Quantitative	Metric tonnes (t)	HC-BP-250a.4
	Number of enforcement actions taken in response to violations of good manufacturing practices (GMP) or equivalent standards, by type [2]	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 to 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, 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 [3]	Quantitative	Presentation 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 staff	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	Percentage (%)	HC-BP-330a.2

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[2] Note to **HC-BP-250a.5** – The entity shall briefly describe the nature, context and any corrective actions taken because of enforcement actions.

[3] Note to **HC-BP-270a.1** – The entity shall briefly describe the nature, context and any corrective actions taken as because of monetary losses.

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TOPIC	METRIC	CATEGORY	UNIT OF MEASURE	CODE
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 programme or equivalent third-party audit programmes 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 [4]	Quantitative	Presentation 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

Table 2. Activity Metrics

ACTIVITY METRIC	CATEGORY	UNIT OF MEASURE	CODE
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

[4] Note to **HC-BP-510a.1** – The entity shall briefly describe the nature, context and any corrective actions taken because of monetary losses.

Safety of Clinical Trial Participants

Topic Summary

Clinical trials are an essential part of the biotechnology and pharmaceutical products approval process. Clinical trial participant safety is a critical component of an entity's ability to bring a product to market successfully. Oversight of these trials is an important factor in the industry because of the numerous clinical trials conducted by third-party contract research organisations. Biotechnology & Pharmaceuticals entities that manage clinical trials effectively may enhance shareholder value through the incremental revenue associated with new products.

Metrics

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

1 The entity shall describe its oversight of the quality and safety systems used by the clinical research organisations (CROs) it employs to administer clinical trials, such as the type of procedures followed, use and frequency of audits or inspections, and enforcement mechanisms.

1.1 In accordance with World Health Organization (WHO) guidance, a clinical trial (also referenced as an interventional trial) is defined as any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.

1.1.1 Interventions include drugs, cells and other biological products, surgical procedures, radiologic procedures, medical devices, behavioural treatments, process-of-care changes and preventive care.

1.2 A CRO is defined as a scientific organisation (commercial, academic or other) to which the entity has transferred some of its tasks and obligations as the clinical trial sponsor.

2 The entity shall discuss its management process for CROs, categorised by the following regions: North America, Central and Latin America, Europe, 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 it employs.

3.1 Reimbursements for meal, travel or lodging are excluded from the description scope.

4 The entity shall describe the process for obtaining clinical trial participant informed consent.

4.1 Informed consent requires more than legally effective acceptance of clinical trial participation. Informed consent also involves the entity:

4.1.1 disclosing to potential research subjects the information needed to make an informed decision;

4.1.2 facilitating the understanding of what has been disclosed; and

4.1.3 promoting the voluntariness of the decision about whether to participate in the research.

5 The entity shall list all clinical trials conducted by the entity that were terminated for failure to follow good clinical practice standards (GCP).

5.1 GCP standards are defined by the International Conference for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use's (ICH) topic E6, *Guideline for Good Clinical Practice* and may be administered under applicable jurisdictional laws or regulations.

6 The entity shall list all clinical trials terminated, whether the investigators or the study sponsor made the decision, and whether the input of a data monitoring committee (DMC) informed the decision.

7 The disclosure shall exclude clinical trials terminated for reasons other than those related to GCP, such as funding reallocation, loss of staff, failure to meet study benchmarks or a lack of participants.

8 The disclosure scope includes the entity's management process with respect to all CROs with which it has worked during the reporting period or in prior periods and plans to use in the future.

HC-BP-210a.2. Number of inspections related to clinical trial management and pharmacovigilance that resulted in: (1) entity voluntary remediation or (2) regulatory or administrative actions taken against the entity

1 The disclosure scope includes all applicable jurisdictional legal or regulatory authority inspections of clinical investigators conducting clinical trials for the entity or on behalf of the entity, such as at a clinical research organisation (CRO).

1.1 Minimum clinical trial inspection criteria should include: protecting the rights, safety and welfare of human research subjects; verifying the accuracy, reliability and integrity of clinical trial data; and assessing compliance with applicable jurisdictional law or regulations governing clinical trial conduct, including informed consent and ethical review.

2 The entity shall disclose the number of inspections related to its own clinical trials that identify objectionable clinical conditions or clinical trial practices resulting in:

2.1 the entity voluntarily taking necessary actions to remediate the conditions or practices found objectionable; or

2.2 the entity facing regulatory or administrative actions or penalties under applicable jurisdictional laws or regulations for failing to meet clinical trial compliance or related licensing standards or guidelines.

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 incurred during the reporting period resulting from legal proceedings associated with clinical trials in developing countries.

1.1 The scope of the disclosure shall include legal proceedings associated with clinical trials in countries that meet the criteria established by the most recent Access to Medicine Foundation's *Access to Medicine Index*.

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, verdict after trial or otherwise), including fines and other monetary liabilities incurred during the reporting period as a result of civil actions (for example, civil judgements or settlements), regulatory proceedings (for example, penalties, disgorgement or restitution) and criminal actions (for example, criminal judgements, penalties or restitution) brought by any entity (for example, governmental, business or individual).

4 The scope of monetary losses shall exclude legal and other fees and expenses incurred by the entity in its defence.

5 The scope of the disclosure shall include legal proceedings associated with the enforcement of applicable jurisdictional laws or regulations.

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

1 The entity shall briefly describe the nature (for example, judgement or order issued after trial, settlement, guilty plea, deferred prosecution agreement or non-prosecution agreement) and context (for example, failure to obtain informed consent) of all monetary losses resulting from legal proceedings.

2 The entity shall describe any corrective actions implemented in response to the legal proceedings. This may include specific changes in operations, management, processes, products, business partners, training or technology.

Access to Medicines

Topic Summary

Biotechnology and pharmaceuticals entities play an important role in providing access to the industry's products around the world. Entities may develop product pricing frameworks that account for varying levels of economic development and different health care needs across various countries. Strategies related to improving access to medicines may yield growth opportunities, innovation and unique partnerships, which may enhance shareholder value.

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 in which it participated during the reporting period related to improving access to health care products for priority diseases and in priority countries.

2 The entity shall discuss products authorised 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 should indicate this condition, however.

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; and

4.7 philanthropic activities.

5 Priority diseases and priority countries are defined as the diseases and countries included in the most recent Access to Medicine Foundation's *Access to Medicine Index*.

6 The disclosure shall focus on initiatives related to the priority diseases, conditions and pathogens.

7 The entity may discuss additional or alternative diseases, conditions and pathogens but should provide evidence that they are considered priority diseases in the priority countries discussed.

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 authorised for sale and available during the reporting period 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 (for example, 30 mg or 20 mg) or in different formulations (for example, tablet or capsule) shall be counted once.

1.2 Listings of single APIs (for example, Lamivudine) and combinations of the same API with one or more additional APIs (for example, 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 non-proprietary name (INN), including brand names in parentheses where applicable.

3 The entity may disclose the number of its products targeting each WHO-defined therapeutic area, which may include:

3.1 diarrhoea;

3.2 HIV/AIDS;

3.3 influenza;

3.4 malaria; and

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 may continue to place downward pricing pressures on the Biotechnology & Pharmaceuticals industry. As a result, entities that have relied on raising drug prices, contractual advantages and reverse payments to protect profits may be challenged by efforts to reduce costs. Entities that effectively manage their global pricing practices and associated stakeholder scrutiny of pricing practices may limit their risk exposure to regulatory action or adverse reputational effects.

Metrics

HC-BP-240b.2. Percentage change in: (1) weighted average list price and (2) weighted average net price across product portfolio compared to previous reporting period

1 The entity shall disclose (1) the annualised percentage change in the revenue-weighted average list price increase across all the entity's pharmaceutical products sold globally during the reporting period.

1.1 The average list price increase shall be calculated as the annualised percentage change versus the reporting period for each product weighted by list price across the entity's global pharmaceutical product portfolio.

1.2 The list price shall be calculated as the revenue-weighted average wholesale acquisition cost (WAC) for the reporting period being calculated.

2 The entity shall disclose (2) the annualised percentage change in the revenue-weighted average net price increase across all the entity's pharmaceutical products sold globally during the reporting period.

2.1 The average net price increase shall be calculated as the annualised percentage change in net price compared to the prior reporting period for each product across the entity's global pharmaceutical product portfolio.

2.2 The net price shall be calculated as the revenue-weighted average WAC minus rebates, discounts and returns for the reporting period being calculated.

3 The entity may disaggregate the disclosures by product type (for example, brand name and generic), region, or another relevant categorisation.

4 The entity may discuss additional context regarding price changes by the categories chosen, including its strategy for determining product pricing by category.

5 The entity may disclose comparative presentation currency inflation data by providing the percentage change in the broadest relevant measure of indexed consumer prices concurrent with the reporting period. If making this disclosure, the entity shall identify the trusted source of that inflation data.

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

1 The entity shall disclose (1) the annualised percentage change in list price and the name of the product with the largest increase in list price compared to the previous reporting period.

1.1 The change in net price increase shall be calculated as the annualised percentage change in list price between the current and prior reporting period for an individual product.

1.2 List price should be calculated as the average wholesale acquisition cost (WAC) for the specific product and shall represent the average WAC for the reporting period being calculated.

2 The entity shall disclose (2) the annualised percentage change in net price and the name of the product with the largest increase in net price compared to the previous reporting period.

2.1 The change in net price increase should be calculated as the annualised percentage change in net price between the current and prior reporting period for an individual product.

2.2 The net price shall be calculated as the average WAC minus rebates, discounts and returns for the specific product for the reporting period being calculated.

3 The entity may disaggregate the disclosures by product type (for example, brand name and generic), region, or another relevant categorisation.

4 The entity may discuss additional context regarding price changes by the categories chosen.

5 The entity may disclose comparative presentation currency inflation data by providing the change in the broadest relevant measure of indexed consumer prices concurrent with the reporting period. If making this disclosure, the entity shall identify the trusted source of that inflation data.

Drug Safety

Topic Summary

Important product safety information may be discovered after controlled clinical trials and regulatory approval. Subsequently, entities may be exposed to the financial implications of associate adverse events and product recalls. Product safety concerns, manufacturing defects or inadequate disclosure of product-related risks may result in significant product liability claims. Biotechnology & Pharmaceuticals entities that mitigate the incidence of product recalls, safety concerns and enforcement actions may better preserve shareholder value. In addition, concern over the abuse or resale of certain medications has resulted in the development of mandated take-back programmes. Entities that successfully engage in these programmes may limit future liabilities.

Metrics

HC-BP-250a.1. Products listed in public medical product safety or adverse event alert databases

1 The entity shall disclose all drugs and therapeutic biological products associated with the entity listed in public medical product safety or adverse event alert databases in response to indications of potentially serious risks or product safety issues.

1.1 The scope of the disclosure includes listings associated with the entity or its subsidiaries, including trade names for which the entity has patents, or active ingredients or classes of product that it manufactures or markets.

1.2 The scope of the disclosure includes the World Health Organization's (WHO) VigiBase maintained by the Upsala Monitoring Centre or any comparable regional or global pharmacovigilance database platform supporting jurisdictional laws or regulations.

2 If a product, a product with an active ingredient or a product in a product class is listed in more than one pharmacovigilance database, the entity may treat these entries as a single listing.

3 If the entity manufactures a product, a product with an active ingredient or a product in a product class listed in these databases but has evidence that the safety alert listing does not apply to its specific products, the entity may disclose such evidence.

4 The entity shall disclose the public medical product safety or adverse event alert database(s) used to compile the list of products.

HC-BP-250a.2. Number of fatalities associated with products

1 The entity shall disclose the total number of fatalities associated with all products it manufactures.

2 The scope of the disclosure shall include all fatalities that occurred during the reporting period, even if the adverse event began during a prior period.

3 The entity may access a list of fatalities through an applicable jurisdictional legal or regulatory adverse event reporting system or database.

4 The entity shall disclose the adverse event reporting system or database used to calculate the number of reported fatalities.

HC-BP-250a.3. (1) Number of recalls issued, (2) total units recalled

1 The entity shall disclose (1) the total number of product-safety recalls for products that the entity manufactures issued during the reporting period.

1.1 Product-safety recalls are defined as actions taken by an entity to remove a product from the market related to potential or actual adverse health consequences resulting from prescribed product use. This includes recalls conducted on the entity's own initiative, or as requested or mandated by applicable jurisdictional legal or regulatory authorities.

1.2 Products include:

1.2.1 pharmaceutical prescription products as well as over-the-counter medications; and

1.2.2 biological products.

1.3 The scope of the disclosure shall include recalls associated with all products manufactured by the entity or by its subsidiaries.

2 The entity shall disclose recalls initiated voluntarily that have not been requested or mandated by applicable jurisdictional legal or regulatory authorities or are not listed in a regulatory authority recall report.

3 The entity shall disclose (2) the total number of drug units subject to product-safety recalls.

4 The entity may disclose revenues for each recalled product 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 disclose the annual revenues associated with the product such that the recall's financial effects can be accurately measured.

5 If a recall relates to only a subset of a product (for example, specific lots), then the entity should explain the scope of the recall. If the entity is disclosing revenue associated with the recall, it should be limited to the portion of the product affected by the recall.

6 The entity shall discuss notable recalls, such as those that affected a significant number of units of a given product or those related to serious illnesses or fatalities. For such recalls, the entity may provide:

6.1 a description and cause of the recall issue;

6.2 the total number of units recalled;

6.3 the cost to remedy the issue;

6.4 whether the recall was voluntary or at the request or mandate of applicable jurisdictional legal or regulatory authorities;

6.5 corrective actions; and

6.6 any other significant outcomes (for example, legal proceedings or fatalities).

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

1 The entity shall disclose the weight of unused product, in metric tonnes, 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 programmes include redistribution initiatives aimed at providing medication to underserved populations, subject to applicable jurisdictional laws or regulations.

1.4 Disposal of biopharmaceutical products may include high-temperature incineration conducted in accordance with applicable jurisdictional laws or regulations governing the management of unused pharmaceuticals.

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 product end-of-life management, such as those intended to prevent:

3.1 back-market sales;

3.2 abuse; and

3.3 release into the environment.

4 The entity may disclose expenditures for funding of programmes or initiatives the entity financially supports and administers as well as initiatives the entity funds that are administered by third parties for the express purpose of product take-back.

HC-BP-250a.5. Number of enforcement actions taken in response to violations of good manufacturing practices (GMP) or equivalent standards, by type

1 The entity shall disclose the total number and type of enforcement actions taken during the reporting period in response to violations of good manufacturing practices (GMP) or equivalent facility and manufacturing safety standards under applicable jurisdictional laws or regulations at the sites it operates.

2 Derived from the World Health Organization (WHO) Certification Scheme, GMP are defined as standards to ensure proper design, monitoring and control of facility and manufacturing processes in pharmaceuticals production.

3 Enforcement actions may include:

3.1 non-compliance violations or issues identified during safety inspections;

3.2 warning letters;

3.3 seizures;

3.4 recalls; and

3.5 consent decrees.

4 The scope of the disclosure includes facilities 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 implemented in response to each incident. This may include specific changes in operations, management, processes, products, business partners, training or technology.

Counterfeit Drugs

Topic Summary

Fake or substandard medication presents a significant risk to consumers in all countries. Biotechnology & Pharmaceuticals entities may face added costs as jurisdictions implement drug supply chain regulations to prevent counterfeit, substandard or mislabelled drugs from entering the pharmaceutical distribution system. Entities that fail to manage this issue effectively may face material risks associated with the loss of public confidence and reduced revenue.

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 of technology it uses to maintain traceability and serialisation, as well as to prevent counterfeiting of its products, which may include the use of barcode technology and radio frequency identification (RFID) tagging.

1.1 Counterfeit products are defined as drugs sold under a product name without proper authorisation. Counterfeiting can apply to both brand name and generic products, if the source identity is mislabelled in a way that suggests that the imitation drug 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 (for example, 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 may include:

2.1 drug wholesale and distribution;

2.2 manufacturing;

2.3 pharmacy retail; or

2.4 transportation logistics.

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

1 The entity shall discuss how it alerts customers and business partners to potential or known risks associated with counterfeit products.

1.1 Customers may include patients and physicians.

1.2 Business partners may include suppliers, wholesalers, retailers and hospitals.

1.3 Counterfeit products are defined as drugs sold under a product name without proper authorisation. Counterfeiting can apply to both brand-name and generic products, where the source identity is mislabelled 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 minimise 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, or filing of criminal charges related to counterfeit products

1 The entity shall disclose the total number of instances in which it took action to alert or aid applicable jurisdictional legal or regulatory authorities to counterfeiting, which may include:

1.1 providing information or evidence that led to raids or arrests of counterfeiters or the seizure of counterfeit products; and

1.2 filing of criminal charges against counterfeiters.

2 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.

3 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 & Pharmaceuticals entities face challenges associated with the marketing of specific products. Direct-to-consumer advertisements for prescription drugs provide opportunities for increasing market share. However, marketing off-label uses may result in significant fines and settlements. Corporate disclosure of legal and regulatory fines and the codes of ethics that govern marketing activities may allow investors to better understand performance in this area.

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 incurred during the reporting period resulting from legal proceedings associated with false marketing claims.

2 The legal proceedings shall include any adjudicative proceeding involving the entity, 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, verdict after trial or otherwise), including fines and other monetary liabilities as a result of civil actions (for example, civil judgements or settlements), regulatory proceedings (for example, penalties, disgorgement or restitution) and criminal actions (for example, criminal judgements, penalties or restitution) brought by any entity (for example, governmental, business or individual).

4 The scope of monetary losses shall exclude legal and other fees and expenses incurred by the entity in its defence.

5 The scope of the disclosure shall include legal proceedings associated with the enforcement of applicable jurisdictional laws or regulations.

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

1 The entity shall briefly describe the nature (for example, judgement or order issued after trial, settlement, guilty plea, deferred prosecution agreement or non-prosecution agreement) and context (for example, off-label promotion) of all monetary losses resulting from legal proceedings.

2 The entity shall describe any corrective actions implemented in response to the legal proceedings. This may include 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 promotion of off-label use of products, including describing how the code defines 'off-label promotion'.

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

3 The entity shall describe the mechanisms it has developed to ensure code compliance, which may include:

3.1 disciplinary actions for violations;

3.2 training;

3.3 internal audits;

3.4 regulatory review committees; and

3.5 training, including degree and frequency of training.

Employee Recruitment, Development & Retention

Topic Summary

Biotechnology & Pharmaceuticals entities face intense competition for recruiting and retaining employees. The industry relies on highly skilled employees to develop new products, conduct clinical trials, manage government regulations and commercialise new products. Entities that attract and retain employees despite a constrained talent pool may be better positioned to protect and enhance shareholder value.

Metrics

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

1 The entity shall describe its strategy to attract and retain talent, which may include:

1.1 mentorship programmes;

1.2 career development programmes;

1.3 leadership training; and

1.4 incentive structures.

2 The entity may describe these elements of staff recruitment and retention programmes, including associated quantitative metrics:

2.1 overview;

2.2 implementation;

2.3 participation; and

2.4 effectiveness.

3 The disclosure shall focus on scientists and other staff 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 the (1) voluntary and (2) involuntary employee turnover rate as a percentage for all employees in these employee categories:

1.1 executives/senior managers, defined as individuals who plan, direct and formulate policies, set strategy and provide the overall direction of enterprises/organisations for the development and delivery of products or services, within the parameters approved by boards of directors or other governing bodies;

1.2 mid-level managers, defined as individuals who serve as managers, other than those who serve as executive/senior managers, including those who oversee and direct the delivery of products, services or functions at group, regional or divisional levels of organisations;

1.3 professionals, defined as individuals who execute tasks but whose role requires a professional degree or certification; and

1.4 all others, defined as employees not counted in the above categories.

2 The entity may refer to the International Standard Classification of Occupations (ISCO) or an applicable jurisdictional occupational classification standard in defining employee categories.

3 The entity shall disclose the occupational classification used to define employee categories, if any.

4 For each category of employee, the entity shall calculate as a percentage (1) the voluntary turnover rate as the number of employee-initiated separations (for example, resignation or retirement) during the reporting period, divided by the average number of workers employed during the reporting period.

5 For each category of employee, the entity shall calculate as a percentage (2) the involuntary turnover rate as the number of entity-initiated separations (for example, dismissal, downsizing, redundancy or non-renewal of contract) during the reporting period, divided by the average number of workers employed during the reporting period.

Supply Chain Management

Topic Summary

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

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 programme or equivalent third-party audit programmes 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 programme or equivalent third-party audit programmes for integrity of supply chain and ingredients.

1.1 An equivalent third-party audit programme 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 programme.

1.2 The scope of the disclosure includes facilities owned or operated by the entity.

1.3 The percentage shall be calculated as the number of the entity's facilities participating in the Rx-360 (or equivalent) audit programme divided by the entity's total number of facilities.

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 programme.

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% of its supplier spending.

2.3 The percentage shall be calculated as the number of the entity's Tier 1 suppliers' facilities participating in the Rx-360 (or equivalent) audit programme divided by the total number of its Tier 1 suppliers' facilities.

Business Ethics

Topic Summary

Biotechnology & Pharmaceuticals entities are subject to various jurisdictional laws and regulations pertaining to bribery, corruption and health care fraud and abuse. The ability of entities 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 their interactions with health care professionals may allow investors to monitor performance in this area.

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 incurred during the reporting period resulting from legal proceedings associated with bribery and corruption.

2 The legal proceedings shall include any adjudicative proceeding involving the entity, 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, verdict after trial or otherwise), including fines and other monetary liabilities incurred during the reporting period as a result of civil actions (for example, civil judgements or settlements), regulatory proceedings (for example, penalties, disgorgement or restitution) and criminal actions (for example, criminal judgements, penalties or restitution) brought by any entity (for example, governmental, business or individual).

4 The scope of monetary losses shall exclude legal and other fees and expenses incurred by the entity in its defence.

5 The scope of the disclosure shall include legal proceedings associated with the enforcement of applicable jurisdictional laws or regulations.

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

1 The entity shall briefly describe the nature (for example, judgement or order issued after trial, settlement, guilty plea, deferred prosecution agreement or non-prosecution agreement) and context (for example, bribery or fraud) of all monetary losses resulting from legal proceedings.

2 The entity shall describe any corrective actions implemented in response to the legal proceedings. This may include 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 its interactions with health care professionals.

1.1 Health care professionals include individuals or entities involved in the provision of health care services or products to patients, such as physicians, dentists, pharmacists and nurses. Additionally, the term includes those who purchase, lease, recommend, use, prescribe or arrange for the purchase or lease of the entity's products, but do not necessarily provide health care services directly, for example purchasing agents, practice managers and group purchasing organisations (GPOs).

1.2 The scope of the disclosure includes the content (for example, food and entertainment, training and education, and participation in committees that set formularies) of the code of ethics, as well as its scope (the type and percentage of staff to which it relates).

2 Corporate policies, codes of conduct, guidelines or contractual terms that are similar in intent to a code of ethics shall be treated as equivalent to a code of ethics for the purposes of this metric.

3 The entity shall discuss the organisational mechanisms used to ensure compliance with its code, which may include:

3.1 enforcement, including inspection, compliance and review committees;

3.2 implementation of corrective actions if a code is violated; and

3.3 training, including degree and frequency of training.

4 If the entity has adopted a second- or third-party code of ethics, the entity may reference this code without describing its content.

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