

# **Medical Equipment & Supplies**

Sustainability Accounting Standard

**HEALTH CARE SECTOR** 

## Sustainable Industry Classification System® (SICS®) HC-MS

Under Stewardship of the International Sustainability Standards Board

INDUSTRY STANDARD | VERSION 2023-12





#### **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.

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#### 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 Medical Equipment & Supplies industry researches, develops and produces medical, surgical, dental, ophthalmic and veterinary instruments and devices. Hospitals, clinics and laboratories use these products, which range from disposable items to highly specialised equipment. The increased prevalence of diseases associated with unhealthy lifestyles and an ageing population are important factors that may encourage growth in this industry. Emerging markets and the expansion of health insurance may contribute to further growth. However, the extension of government insurance programmes, provider and payer consolidation, and regulatory emphasis on reduced costs in all markets may result in downward pricing pressure.

#### SUSTAINABILITY DISCLOSURE TOPICS & METRICS

Table 1. Sustainability Disclosure Topics & Metrics

TOPIC	METRIC	CATEGORY	UNIT OF MEASURE	CODE
Affordability & Pricing	Description of how price information for each product is disclosed to customers or to their agents	Discussion and Analysis	n/a	HC-MS-240a.2
	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-MS-240a.3
Product Safety	(1) Number of recalls issued, (2) total units recalled	Quantitative	Number	HC-MS-250a.1
	Products listed in any public medical product safety or adverse event alert database	Discussion and Analysis	n/a	HC-MS-250a.2
	Number of fatalities associated with products	Quantitative	Number	HC-MS-250a.3
	Number of enforcement actions taken in response to violations of good manufacturing practices (GMP) or equivalent standards, by type <sup>1</sup>	Quantitative	Number	HC-MS-250a.4
Ethical Marketing	Total amount of monetary losses as a result of legal proceedings associated with false marketing claims <sup>2</sup>	Quantitative	Presentation currency	HC-MS-270a.1
	Description of code of ethics governing promotion of off-label use of products	Discussion and Analysis	n/a	HC-MS-270a.2
Product Design & Lifecycle Management	Discussion of process to assess and manage environmental and human health considerations associated with chemicals in products, and meet demand for sustainable products	Discussion and Analysis	n/a	HC-MS-410a.1
	Total amount of products accepted for take-back and reused, recycled or donated, broken down by: (1) devices and equipment and (2) supplies	Quantitative	Metric tonnes (t)	HC-MS-410a.2

continued...

Note to HC-MS-250a.4 - The entity shall briefly describe the nature, context and any corrective actions taken because of enforcement

<sup>&</sup>lt;sup>2</sup> Note to **HC-MS-270a.1** – The entity shall briefly describe the nature, context and any corrective actions taken because of monetary losses.

#### ...continued

TOPIC	METRIC	CATEGORY	UNIT OF MEASURE	CODE
Supply Chain Management	Percentage of (1) entity's facilities and (2) Tier 1 suppliers' facilities participating in third-party audit programmes for manufacturing and product quality	Quantitative	Percentage (%)	HC-MS-430a.1
	Description of efforts to maintain traceability within the distribution chain	Discussion and Analysis	n/a	HC-MS-430a.2
	Description of the management of risks associated with the use of critical materials	Discussion and Analysis	n/a	HC-MS-430a.3
Business Ethics	Total amount of monetary losses as a result of legal proceedings associated with bribery or corruption <sup>3</sup>	Quantitative	Presentation currency	HC-MS-510a.1
	Description of code of ethics governing interactions with health care professionals	Discussion and Analysis	n/a	HC-MS-510a.2

Table 2. Activity Metrics

ACTIVITY METRIC	CATEGORY	UNIT OF MEASURE	CODE
Number of units sold by product category	Quantitative	Number	HC-MS-000.A

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

## Affordability & Pricing

#### **Topic Summary**

Health care cost containment and health care access regulatory initiatives may place downward pricing pressures on the Medical Equipment & Supplies industry. This pressure may be increased further by consolidation among health care providers and the role of government-sponsored insurance programmes. Entities that ensure fair pricing may limit the negative effects of cost containment as well as benefitting from the potential revenue opportunities associated with expanded access. Entities that successfully balance the risks and opportunities associated with cost containment and improved access to health care may increase their market share among segments of the population that might ordinarily be less likely to seek health care.

#### **Metrics**

# HC-MS-240a.2. Description of how price information for each product is disclosed to customers or to their agents

- 1 The entity shall describe the nature, scope and implementation of policies and initiatives related to providing price information to customers, specifically indicating which aspects of the price (for example, the range, median or typical price), if any, are provided to customers.
  - 1.1 Customers shall be considered those purchasing directly from the entity or through intermediaries, such as group purchasing organisations (GPOs) or consultants negotiating on behalf of the customer.
- 2 The entity shall describe the frequency with which it uses purchasing agreement confidentiality clauses with health care providers that restrict them from sharing the price paid for the entity's products with third parties.
- 3 The entity may discuss factors that affect pricing, which may include:
  - 3.1 the entity's product volume;
  - 3.2 the region in which the customer is located; or
  - 3.3 the type of facility the customer is operating.

# HC-MS-240a.3. 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 across all the entity's medical equipment and supplies products sold globally during the reporting period.
  - 1.1 The average list price increase shall be calculated as the annualised percentage change in list price compared to the prior reporting period for each product across the entity's global medical equipment and supplies 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 revenue-weighted average net price across all the entity's 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 medical equipment and supplies 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, 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 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.

## **Product Safety**

#### **Topic Summary**

Information on product safety and side effects may be discovered after controlled clinical trials and approval. In such cases, entities are exposed to the financial implications of recalls and other adverse events, such as unfavourable media coverage, fines or investigations. Issues related to product safety, such as equipment failures, manufacturing defects, design flaws or inadequate disclosure of product-related risks, may result in significant product liability claims. Entities that limit the incidence of recalls, safety concerns and enforcement actions for manufacturing concerns may better protect shareholder value.

#### **Metrics**

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

- 1 The entity shall disclose (1) the total number of product-safety recalls for medical devices and supplies that it 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 use. This includes recalls conducted by the entity voluntarily, as well as those requested or mandated by a regulatory authority.
  - 1.2 The scope of the disclosure shall include recalls associated with all devices 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 jurisdictional regulatory recall report.
- 3 The entity shall disclose (2) the total number of device units subject to product-safety recalls.
- 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 of the recall can be accurately measured.
- 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, the disclosure 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 injuries 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-MS-250a.2. Products listed in any public medical product safety or adverse event alert database

- 1 The entity shall disclose all products associated with the entity that are listed in any public medical product safety or adverse event alert database in response to indications of potentially serious risks or product safety issues.
  - 1.1 The scope of the disclosure includes all listings associated with the entity or its subsidiaries, including trade names for which the entity has patents, or classes of products that it manufactures or markets.
  - 1.2 The scope of the disclosure includes any medical product safety or adverse alert database maintained under applicable jurisdictional laws or regulations, or any comparable regional or global medical device pharmacovigilance database platforms supporting local authority efforts.
- 2 If a product, a product with a component or a product in a product class is listed in more than one medical device pharmacovigilance database, the entity may treat these entries as a single listing.
- 3 If the entity manufactures a product, a product with a component 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.

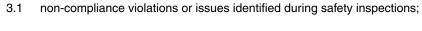
#### HC-MS-250a.3. Number of fatalities associated with products

- 1 The entity shall disclose the total number of fatalities associated with 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-MS-250a.4. 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	GMP are defined as standards to ensure proper design, monitoring and control of facility and manufacturing processes in medical device and medical supplies production.
3	Enforcement actions include:



- 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-MS-250a.4

- 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.

## **Ethical Marketing**

#### **Topic Summary**

Entities in the Medical Equipment & Supplies industry face legal and regulatory challenges associated with product marketing. Direct-to-consumer advertisements for medical devices and outreach to physicians provide opportunities for entities to increase their market share. However, challenges arise from the potential for marketing off-label uses, which 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 develop a better understanding of performance in this area.

#### **Metrics**

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

- The entity shall disclose the total amount of monetary losses incurred during the reporting period resulting from legal proceedings associated with false marketing claims.
- The legal proceedings shall include any adjudicative proceeding involving the entity, whether before a court, a regulator, an arbitrator or otherwise.
- 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).
- The scope of monetary losses shall exclude legal and other fees and expenses incurred by the entity in its defence.
- The scope of the disclosure shall include legal proceedings associated with the enforcement of applicable jurisdictional laws or regulations.

#### Note to HC-MS-270a.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 of all monetary losses resulting from legal proceedings.
- 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.

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

- 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 term that is similar in intent to a code of ethics shall be treated as equivalent to a code of ethics for the purposes of this metric.
- The entity shall describe the mechanisms it has developed to ensure code compliance, including:
  - 3.1 disciplinary actions for violations;
  - 3.2 internal audits;
  - 3.3 regulatory review committees; and
  - 3.4 training, including degree and frequency of training.

## Product Design & Lifecycle Management

#### **Topic Summary**

Medical equipment and supplies entities face increasing challenges associated with the human and environmental impact of the industry's products. Entities may face consumer and regulatory pressure to limit the use of material inputs associated with health concerns, while also addressing issues such as the energy efficiency and end-of-life disposal of specific products. Entities that address these concerns while engaging in efforts to enhance product take-back may satisfy consumer demand and reduce future liabilities better.

#### **Metrics**

# HC-MS-410a.1. Discussion of process to assess and manage environmental and human health considerations associated with chemicals in products, and meet demand for sustainable products

- 1 The entity shall describe its strategic approach to addressing specific environmental and human health impacts of its products, including:
  - 1.1 Energy efficiency of products during use
  - 1.2 Disposal of the products
  - 1.3 Material efficiency
  - 1.4 Product packaging
  - 1.5 Toxicity of materials
- 2 The entity shall only describe design considerations that it can determine will deliver a specific, demonstrable environmental benefit.
  - 2.1 Environmental benefits shall be taken to mean those related to:
    - 2.1.1 Energy consumption
    - 2.1.2 Environmental health
    - 2.1.3 Human health
    - 2.1.4 Waste generation
    - 2.1.5 Water use
- 3 The entity shall provide an indication of how central the environmental benefit imparted is to functionality of products.

- 4 The entity shall make the environmental benefit determination in good faith and clarify whether the benefit relates to the product, package or service, avoiding a general statement of environmental benefits and following guidance from applicable laws and statutes.
- 5 The entity shall specify during which lifecycle stage(s) it assesses the environmental impacts associated with its products.
- 6 The entity shall reference the mechanism through which it implements efforts, including:
  - 6.1 Use of design protocols
  - 6.2 Procurement policies
  - 6.3 Restricted substances lists (RSLs)
  - 6.4 Certifications
  - 6.5 Product take-back programmes
  - 6.6 Packaging take-back
- 7 For efforts related to the end-of-life of product management, the entity shall discuss only design-related considerations.
- 8 The entity shall disclose the percentage of products, by revenue, for which it has integrated environmental considerations into the design.

# HC-MS-410a.2. Total amount of products accepted for take-back and reused, recycled or donated, broken down by: (1) devices and equipment and (2) supplies

- 1 The entity shall disclose the amount, in metric tonnes, of its products that it recovered and reused (refurbished), recycled or donated.
  - 1.1 This figure shall be broken down into: (1) devices and equipment and (2) supplies.
    - 1.1.1 Devices and equipment include high-value machines and advanced devices.
    - 1.1.2 Supplies include simple supplies and low-cost equipment (for example, scalpels, gloves and thermometers).
  - 1.2 This figure shall exclude products accepted for take-back but ultimately discarded as waste.
    - 1.2.1 The entity may disclose if it reclaimed any products it was unable to reuse or recycle because proper, safe disposal was necessary.
- 2 The entity shall describe programmes and initiatives it implements, funds or participates in that are related to product take-back for end-of-life management of its products.

## Supply Chain Management

#### **Topic Summary**

Supply chain quality is essential to protecting consumer health and corporate value. Entities that fail to ensure quality and traceability throughout their supply chains may be susceptible to fines, lost revenue and reputational damage. Additionally, entities may need to manage the use of material inputs that are considered scarce. Disclosure of supply chain audit programmes, strategies to ensure traceability and management of critical materials may better inform investors how entities in this industry are protecting shareholder value.

#### **Metrics**

# HC-MS-430a.1. Percentage of (1) entity's facilities and (2) Tier 1 suppliers' facilities participating in third-party audit programmes for manufacturing and product quality

- 1 The entity shall disclose (1) the percentage of its facilities that participate in third-party audit programmes intended to maintain the quality of manufacturing, management or products, including materials and components.
  - 1.1 A third-party audit programme is one conducted by an external auditing agency to a recognised, independent standard.
  - 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 its facilities participating in third-party audit programmes divided by the number of total entity's facilities.
- 2 The entity shall disclose (2) the percentage of its Tier 1 suppliers' facilities that participate in third-party audit programmes, such as to ISO 13485, Medical devices—Quality management systems—Requirements for regulatory purposes.
  - 2.1 Tier 1 suppliers are those that transact directly with the entity.
  - 2.2 The entity may limit its disclosure to 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 its Tier 1 suppliers' facilities participating in third-party audit programmes divided by the total number of Tier 1 facilities with which it transacts.

# HC-MS-430a.2. Description of efforts to maintain traceability within the distribution chain

- 1 The entity shall discuss the type of technology used to maintain traceability of its products.
  - 1.1 Traceability refers to the ability to track identifying information (for example, production date, production location or processing history) of a product throughout various stages of manufacturing and distribution.

- 1.2 Relevant stages of manufacturing and distribution include:
  - 1.2.1 raw material sourcing;
  - 1.2.2 production;
  - 1.2.3 point of delivery at the health care provider's facilities;
  - 1.2.4 product retail and wholesale; and
  - 1.2.5 transportation logistics.
- 2 The discussion may include the use of:
  - 2.1 barcode technology;
  - 2.2 chain of custody audits; or
  - 2.3 radio frequency identification (RFID) tagging.

# HC-MS-430a.3. Description of the management of risks associated with the use of critical materials

- 1 The entity shall describe how it manages the risks associated with the use of critical materials in its products, including physical limits on availability and access, changes in price, and regulatory and reputational risks, in which:
  - 1.1 a critical material is defined as a material both essential in use and subject to the risk of supply restriction; and
  - 1.2 examples of critical materials include:
    - 1.2.1 antimony, cobalt, fluorspar, gallium, germanium, graphite, indium, magnesium, niobium, tantalum and tungsten;
    - 1.2.2 platinum group metals (platinum, palladium, iridium, rhodium, ruthenium and osmium); and
    - 1.2.3 rare earth elements, which include yttrium, scandium, lanthanum and the lanthanides (cerium, praseodymium, neodymium, promethium, samarium, europium, gadolinium, terbium, dysprosium, holmium, erbium, thulium, ytterbium and lutetium).
- 2 The entity shall identify the critical materials that present a significant risk to its operations, the type of risks they represent and the strategies the entity uses to mitigate the risks.
  - 2.1 Relevant strategies may include diversification of suppliers, stockpiling of materials, development or procurement of alternative and substitute materials, and investments in recycling technology for critical materials.

- 3 All disclosure shall be sufficient such that it is specific to the risks the entity faces, but that disclosure itself would not compromise the entity's ability to maintain confidential information.
  - 3.1 For example, if an entity determines not to identify a specific critical material that presents a significant risk to its operations because of the competitive harm that could result from the disclosure, the entity shall disclose the existence of such risks, the type of risks and the strategies used to mitigate the risks, but the entity is not required to disclose the relevant critical material.

### **Business Ethics**

#### **Topic Summary**

Entities in the Medical Equipment & Supplies industry are subject to various international, national and local laws pertaining to health care fraud and abuse. An entity's ability to ensure compliance throughout its global and domestic operational footprint may have notable effects on enterprise viability and reputation. Corporate disclosure of legal and regulatory fines and the codes of ethics that govern interactions with health professionals may better allow investors to monitor performance in this area.

#### **Metrics**

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

- The entity shall disclose the total amount of monetary losses incurred during the reporting period resulting from legal proceedings associated with bribery or 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-MS-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-MS-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 items 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 shall include 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 mechanisms to ensure compliance with its code of ethics, 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 the code without describing its content.

