

Overview

ESG Issues for Medical Equipment & Supplies Companies

Michelle Williams, Clifford Chance

**Bloomberg
Law**

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Contributed by [Michelle Williams](#), Clifford Chance

Editor's Note: In an effort to simplify the sustainability disclosure landscape, the [International Financial Reporting Standards \(IFRS\) Foundation](#) formed the [International Sustainability Standards Board \(ISSB\)](#) in November 2021. The IFRS is a not-for profit organization dedicated to the development of globally accepted accounting and sustainability disclosure standards. ISSB was tasked with creating a global baseline of sustainability-related disclosure standards.

The IFRS then consolidated Climate Disclosure Standards Board (CDSB) with the [Value Reporting Foundation](#)—which led SASB and the [Integrated Reporting Framework](#)—in August 2022. Since this consolidation, the ISSB has [committed](#) to building on the industry-based [SASB Standards](#).

The [Sustainability Accounting Standards Board \(SASB\)](#) is an independent standards-setting organization that assists companies with the disclosure of financially material sustainability information to investors. See [Overview - Sustainability Accounting Standards Board \(SASB\)](#).

Medical equipment and supplies cover a range of products, devices, and instruments, with companies focused on research and development, production/manufacturing, and marketing/sales (Medical Equipment and Supplies). Medical Equipment and Supplies are used in a variety of settings, including hospitals and clinics, and can range from relatively inexpensive disposable items to high value equipment. Medical Equipment and Supplies address all varieties of medical issues and sub-specialities in the medical field, with demand increasing in line with an aging US population.

Companies in this industry face increasing pressure in terms of pricing, innovation, and commitment to ethical and environmental, social, and governance (ESG) standards. Disclosures by companies in this sector can help protect shareholder value and proactively prepare a company for regulatory enquiries.

SASB Standards

The Sustainability Accounting Standards Board (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. The SASB has developed industry-specific sustainability accounting standards, including for Medical Equipment and Supplies.

Use of SASB Standards is completely voluntary. However, they are designed to enable communications on corporate performance on industry-level sustainability issues by using existing disclosure and reporting mechanisms. SASB notes that use of the Standards can benefit businesses by improving transparency, risk management, and performance. It is important to note that it remains up to the company to determine how it reports SASB information to investors and that in some jurisdictions, but importantly not all, the SASB Standards will assist a company in achieving regulatory compliance.

While the SASB cannot address all financially material sustainability risks or opportunities unique to Medical Equipment and Supplies companies' business models, it provides a helpful framework and starting point.

The SASB Standards cover six disclosure topics with accompanying accounting metrics. The below addresses those six and offers additional topics for further consideration.

Affordability & Pricing

SASB recommends that Medical Equipment and Supplies companies disclose both price increases and how pricing information is provided to customers, in part to fulfil legislative emphasis on containing health care cost. It also observes that companies that can reflect fair pricing will likely help control cost while also realizing potential revenue opportunities.

Under the SASB the following disclosures shall be made:

- Ratio of weighted average rate of net price increases for all products to the annual increase in the US Consumer Price Index.
- Description of how price information is provided to customers.

- Description of frequency with which the company uses confidentiality clauses in purchasing agreements that prohibit sharing of price information with third parties.

Product Safety

Product safety can lead to significant product liability claims which in turn may decrease shareholder value.

Under the SASB the following disclosures shall be made:

- The total number of recalls for medical devices the company manufactures and details relating to the recall, including revenue from the product recalled and whether there were a significant number of units recalled and/or recalls related to serious injuries or fatalities.
- Details regarding voluntarily initiated recalls as well as recalls initiated at the request of non-US national regulatory authorities.
- Number and type of [US Food and Drug Administration \(FDA\) enforcement actions](#).

For more general information on product liability, see [Overview - ESG Product Liability Risks](#).

Ethical Marketing

Competition for market share of Medical Equipment and Supplies means that companies rely both on direct consumer marketing as well as direct marketing to medical providers to try and increase market share. Marketing is an area for potential missteps, including marketing of off-label uses of Medical Equipment and Supplies that can lead to significant regulatory fines and penalties.

Under the SASB the following disclosures shall be made:

- Total monetary losses because of legal proceedings associated with false marketing claims, details, and context of the claims/legal proceedings as well as any related corrective actions taken by the company.
- Regarding the company's code of ethics that relates to ethical marketing and off-label promotions.
- Description of compliance mechanisms to ensure compliance with the company's code of ethics requirements.

Product Design & Lifecycle Management

Shareholders and investors are increasingly concerned and focused on the impact that companies make on the environment or impact general health and safety. This extends both to the manufacturing process and the end-of-life disposal of the products.

Under the SASB the following disclosures shall be made:

- Details on the company's strategic approach to addressing specific environmental and human health impacts of its products, including with respect to energy efficiency, disposal, product packaging and toxicity of materials.
- Description of the amount of the company's products that it recovered, reused (refurbished), recycled, or donated, including details of any programs or initiatives that are related to product "take backs."

Supply Chain Management

The term "supply chain" has become front of mind in recent years, mostly due to its impact on delivering goods—or not delivering goods—to consumers. Understanding where goods are sourced across a company's value chain and the steps a company takes to audit its supply chain are important for protecting shareholder value.

Under the SASB the following disclosures shall be made:

- The percentage of the company's facilities that participate in third-party audit programs intended to maintain the quality of manufacturing, management, and/or products, including materials and components.
- Type and sophistication of technology the company uses to maintain traceability of its products.
- Description of the company's strategic approach to managing its risks associated with the use of critical materials in its products, including identifying the critical materials that present a significant risk to its operations and the strategies the entity uses to mitigate the risk(s).

Business Ethics

Health care fraud is all too prevalent, given the incentive to sell and encourage the use of medical devices in a crowded market. Violations of statutes such as the [Foreign Corrupt Practices Act](#) (FCPA) can result in hefty fines and huge reputational harm where bribery and corruption are uncovered. For information medical devices and FCPA compliance, see [Checklist - FCPA Compliance for Medical Device Companies](#). For general FCPA information, see [In Focus: FCPA](#).

Under the SASB the following disclosures shall be made:

- The total amount of monetary losses incurred during the reporting period as a result of legal proceedings associated with bribery or corruption as well as a description of the nature and context of the legal proceedings as well as any corrective actions.
- Description of code of ethics that relate to interactions with health care professionals as well as mechanisms to ensure compliance with its code of ethics.
- Disclosure of any second- or third-party code of ethics adopted by the company.

For general information on health fraud, see [Practical Guidance: Fraud & Abuse](#).

Additional Disclosure Topics

While not enumerated in the SASB Standards, Medical Equipment and Supplies companies may also want to consider disclosure in the below areas because these factors may also impact risk management, reputational, and safeguarding shareholder value:

- Employee recruitment, development, and retention, including disclosures relating to diversity.
- Privacy and related-cyber security risks, including auditing of controls and disclosure of breaches.