Checklist

ESG Disclosures for Medical Equipment & Supplies Companies (Annotated)

Michelle Williams, Clifford Chance

Bloomberg Law

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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 (VRF), which led the Sustainability Accounting Standards Board (SASB) and the Integrated Reporting Framework, in August 2022. Since this consolidation, the ISSB has committed to building on the industry-based SASB Standards.

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).

For an overview of issues in this industry, see Overview - ESG Issues for Medical Equipment & Supplies Companies.

Contributed by Michelle Williams, Clifford Chance

1. Establishing an ESG Program

Practice Tip: Investors are looking for higher quality quantitative and qualitative disclosures on ESG matters. Robust ESG disclosures should be grounded in an effective company-wide ESG program.

☐ The committee should engage with in-house counsel, third-party advisers, senior management and the board, shareholders, and other stakeholders on a materiality assessment and ESG targets/goals. See Checklist – Stakeholder Engagement.

Practice Tip: Companies may want to carry out a materiality assessment to identify ESG issues that could significantly affect their long-term value creation. A materiality assessment process usually involves cross-departmental collaboration. With experience in dealing with a wide variety of company stakeholders, corporate lawyers are uniquely situated to take the lead with regard to companies' ESG initiatives, including materiality assessment exercises. See Overview - Role of the General Counsel in ESG.

☐ Develop ESG disclosure and reporting policies and procedures.

2. Prepare Disclosures

☐ Determine ESG issues that are financially material for medical equipment and supplies companies and relevant metrics for disclosure purposes. Companies should be able to explain why selected topics and metrics were disclosed.

Practice Tip: According to the Sustainability Accounting Standards Board (SASB), the following ESG issues are financially material for medical equipment and supplies companies. The management or mismanagement of these issues could affect the companies' value creation.

• **Energy & Waste Efficiency:** The manufacturing of medical equipment and supplies requires the use of energy, water, and material inputs and creates waste. As concern over climate change and dwindling natural resources continues to impact pricing, medical equipment and supplies companies will be exposed to fluctuations in costs for these key inputs. Firms that are able to improve manufacturing efficiencies and limit dependence on resources are likely to enhance shareholder value.

• **Product Safety:** Information on product safety and side effects can surface after controlled clinical trials and approval. Subsequently, companies are exposed to the financial implications of recalls and other adverse events.

Equipment failures, manufacturing defects, design flaws, or inadequate disclosure of product-related risks can lead to significant product liability claims. Medical equipment and supplies firms that limit the incidence of these claims will be better positioned to protect shareholder value. For more general information on product liability, see Overview – ESG Product Liability Risks.

• **Ethical Marketing:** Medical equipment and supplies companies face challenges associated with marketing of specific products. Consumer-directed advertisements for medical devices in the US and outreach to physicians provide opportunities for increasing market share. However, challenges arise from the potential for marketing off-label uses. Corporate disclosure of legal and regulatory fines and compliance with the codes of ethics that govern interactions with health professionals will allow shareholders to monitor performance in this area.

• **Affordability & Fair Pricing:** Legislative emphasis in the US and abroad on health care cost containment and increased access will continue to place downward pricing pressures on the medical equipment and supplies industry. This pressure will be further articulated by continued consolidation among health care providers and the increasing role of government-sponsored insurance programs. As a result, companies that have relied on contractual advantages to protect profits may be challenged to enhance value as the government seeks to reduce its Medicare and Medicaid spending. Firms that are able to ensure access and fair pricing are likely to limit the negative impact of cost containment while recognizing the potential revenue opportunities associated with expanded access.

• **Product Design & Lifecycle Management:** Medical equipment and supplies companies face increasing challenges associated with the human and environmental impact of the industry's products. Companies will likely encounter consumer and regulatory pressure to limit the use of toxic and/or scarce material inputs while also addressing issues such as the energy efficiency and end-of-life disposal of specific products. Firms that are able to limit these externalities will be better positioned to meet consumer demand and reduce future liabilities.

• **Corruption & Bribery:** Medical equipment and supplies companies are subject to various state, federal, and international laws pertaining to health care fraud and abuse. For general information on health fraud, see Practical Guidance: Fraud & Abuse. Anti-kickback laws and the Foreign Corrupt Practices Act (FCPA) generally prohibit companies from making payments for the purpose of obtaining or retaining business. The ability of companies to ensure compliance both in the US and abroad is likely to have material implications. For information medical devices and FCPA compliance. See Checklist – FCPA Compliance for Medical Device Companies. For more general information on the FCPA, see In Focus: FCPA.

• **Manufacturing & Supply Chain Management:** Manufacturing and supply chain quality is essential to protecting consumer health and corporate value. Medical equipment and supplies firms that fail to manage quality in these areas are susceptible to significant fines, lost revenue associated with manufacturing stoppages, and the potential loss of independence. Disclosure of Federal Drug Administration enforcement actions and supply chain audit programs provide shareholders with an understanding of how companies in this industry are managing the associated risks.

☐ Review ESG disclosures made by peer companies and competitors.

☐ Consider the target audience in drafting disclosures.

☐ Present disclosures in plain English, without technical jargon.

☐ Use aspirational language. Disclosures should avoid language that could be interpreted as a firm commitment, as opposed to an aspirational goal, and include appropriate disclaiming language.

Practice Tip: Targets phrased in aspirational language are less likely to be considered false or misleading for purposes of securities law liability.

☐ Because of the greater legal liability with respect to disclosures included in documents filed with the SEC–Form 10-Ks and proxy statements–companies should carefully consider the location of the disclosure.

Practice Tip: There is still the possibility of liability for fraud with respect to intentional misstatements made in sustainability reports that are not filed with the SEC. Companies may face enforcement action or private litigation as a result of knowing or reckless misstatements or omissions of material facts.

☐ Involve the corporate compliance officer or similar official in the review process for any ESG disclosures to make sure they are properly validated and qualified because of potential liability.

☐ Companies may want to consider drafting a separate "Sustainability Discussion and Analysis" (SD&A) section in their financial reports.

Practice Tip: Under SEC rules, an SD&A discussion is not required in the financial statements to investors. However, companies should be prepared for the possibility that the SEC might adopt such a provision. The SEC is currently reviewing its ESG disclosure rules and has previously required a narrative discussion of corporate practices when mandating a Compensation Discussion & Analysis review for executive pay. Companies that draft an SD&A section in their financial reports could get ahead of the curve with regard to their peers if the SD&A discussion becomes mandatory.

☐ Disclosures should be consistent across all public statements by the company, including marketing and promotional materials.

☐ Disclosures should be complete and specific, but they should not be lengthy or repetitive.

☐ Disclose areas for improvement.

Practice Tip: Companies are not perfect. Even with a robust ESG program in place, progress can still be made. Identify where the company can do better.