



Public Exposure Draft for the sole purpose of SASB's 30-Day Public Comment Period

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Biotechnology

Category	ESG Issue	Key Performance Indicator (KPI)	UoM*	KPI Type	Impact/Innovation
Social Capital	Access to Medicines	Ranking and score in the Access to Medicine (ATM) Index.	#	Quantitative	Innovation
		Initiatives, as described by the Access to Medicine (ATM) Foundation, to promote access to healthcare products in priority countries, defined as World Bank Low-Income and Lower Middle-Income Countries (LIC and LMICs) and UN HDI Medium-High Development Countries (MHDCs) that are not captured by the World Bank LIC or LMIC rankings.	n/a	Qualitative	Innovation
		List of products on WHO List of Prequalified Medicinal Products as part of its Prequalification of Medicines Programme (PQP).	#	Quantitative	Innovation
	Drug Safety and Side-Effects	List of products with <i>Potential Signals of Serious Risks</i> or those that have <i>New Safety Information</i> identified by the FDA Adverse Event Reporting System (FAERS).	#	Quantitative	Impact
		List of products in the FDA's MedWatch Safety Alerts for Human Medical Products (Drugs and Therapeutic Biological Products) database.	#	Quantitative	Impact
		Number of fatalities associated with products as reported in the FDA Adverse Event Reporting System.	#	Quantitative	Impact
		List of products recalled, with associated revenue in the 12-month period preceding the recall.	\$	Quantitative	Impact
	Safety of Clinical Trial Participants	List of clinical trials terminated due to serious adverse reactions (including abnormalities in laboratory analyses, vital signs, or outcomes).	#	Quantitative	Impact
		Impact (\$ amount) on projected revenue due to clinical trials slowed or terminated due to serious adverse reactions, failure to follow good clinical practice standards, or new toxicological findings affecting the benefit-to-risk ratio.	\$	Quantitative	Impact
		Discussion of management process for ensuring quality and patient safety during clinical trials conducted with third-party clinical research organizations (CROs), including process for obtaining informed consent and incentives offered to participants, by world region.	n/a	Qualitative	Impact
		Number of FDA Clinical Investigator Inspections of investigators used for clinical trials during the past year that resulted in: (1) Voluntary Action Indicated and (2) Official Action Indicated, as included on the Clinical Investigator Inspection List (CLIL).	#	Quantitative	Impact
		Description of legal and regulatory judgments, fines, and settlements (including \$ amount) related to clinical trials in World Bank Low-Income and Lower Middle-Income Countries (LIC and LMICs) and UN HDI Medium-High Development Countries (MHDCs) that are not captured by the World Bank LIC or LMIC rankings.	\$	Quantitative	Impact
	Affordability, Access, and Fair Pricing	Number of settlements of Abbreviated New Drug Application (ANDA) litigation that involved payments and/or provisions to delay market entry of an authorized generic product for a defined time period.	#	Quantitative	Impact
		Ratio of weighted average rate of net price increases (for all products) to annual increase in U.S. Consumer Price Index.	\$	Quantitative	Impact

*UoM = Unit of Measure

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Biotechnology (continued)

Category	ESG Issue	Key Performance Indicator (KPI)	UoM*	KPI Type	Impact/Innovation
Social Capital	Ethical Marketing	Description of legal and regulatory judgments, fines, and settlements (including \$ amount) related to false marketing claims, including False Claims Act violations for off-label marketing.	\$	Quantitative	Impact
		Description of code of ethics governing interactions with healthcare professionals, including mechanisms to ensure employee compliance.	n/a	Qualitative	Innovation
	Orphan Drugs	Revenue from drugs listed in the FDA's Orphan Drug Product designation database, by category.	\$	Quantitative	Innovation
		Discussion of ongoing efforts to address orphan diseases.	n/a	Qualitative	Innovation
	Chronic Disease Prevention and Treatment	Revenue from drugs targeting obesity prevention and other drugs aimed at preventing chronic, non-communicable diseases (e.g. targeting high cholesterol, high blood pressure, or smoking cessation).	\$	Quantitative	Innovation
	Employee Recruitment, Development, and Retention	Description of talent recruitment and retention efforts for scientists and other research and development personnel, such as mentorship and career development programs, leadership training, or unique incentive structures.	n/a	Qualitative	Innovation
		Training and development expenditure per full time employee by: (1) expenditures for industry or professional qualification and advanced industry education; (2) all other.	\$	Quantitative	Innovation
		Employee turnover by voluntary and involuntary for: Executives/Senior Managers, Mid-level Managers, Professionals, All others (EEO-1 categories technicians, sales, admin support, service workers).	%	Quantitative	Impact
		Total Injury Rate (OSHA) - (Number of recordable injuries and illnesses /Hours worked)*200,000.	#	Quantitative	Impact
		DART rate (OSHA) - (Number of recordable injuries and illnesses resulting in days away from work, restricted work activity, or job transfers /Hours worked)*200,000.	#	Quantitative	Impact
		LAI (laboratory acquired infection) rate = LAIs per 1000 employees in human and animal diagnostic laboratories.	#	Quantitative	Impact
	Counterfeit Drugs	Description of methods and technologies used to maintain traceability of products throughout the supply chain (e.g. RFID, ePedigree, serialization).	n/a	Qualitative	Innovation
		Description of process for alerting customers and business partners of potential or known risks associated with counterfeit products.	n/a	Qualitative	Innovation
		Number (and description) of initiatives or actions that supported raids, seizure, arrests, and/or filing of criminal charges related to counterfeit products.	#	Quantitative	Innovation

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Biotechnology (continued)

Category	ESG Issue	Key Performance Indicator (KPI)	UoM*	KPI Type	Impact/Innovation
Environmental Capital	Pharmaceutical Water Contamination	Describe product stewardship initiatives to promote reuse, take-back, and/or proper disposal of products at the end of their lifecycle. Where applicable, report (1) amount of product (by weight) and (2) amount of direct funding for such initiatives.	n/a	Qualitative	Innovation
		Description of efforts to understand and monitor the effects of pharmaceutical products and their metabolites on ecological and human health throughout the product lifecycle (from manufacturing, use, and disposal).	n/a	Qualitative	Impact
	Resource Efficiency	Total energy consumption (gigajoules) - renewable energy consumption (gigajoules).	GJ	Quantitative	Impact
		Ratio of cost (\$ per gigajoule) of non-renewable energy to renewable energy.	n/a (\$)	Quantitative	Innovation
		Description of risks and opportunities associated with own greenhouse gas emissions.	n/a	Qualitative	Impact
		Water withdrawals in water-stressed regions - High or Extremely High Baseline Water Stress as defined by the WRI Water Risk Atlas.	m ³	Quantitative	Impact
		Water intensity (m ³ of production water per ton of product) in water-stressed regions - High or Extremely High Baseline Water Stress as defined by the WRI Water Risk Atlas.	m ³ /ton	Quantitative	Impact
	Process Mass Intensity (PMI) = quantity of raw materials input (kg) / quantity of active pharmaceutical product (API) output (kg). Report overall PMI and for each of the following inputs: water, organic solvents, reactants, and other.	metric tons	Quantitative	Impact	
Disease Migration	Description of risks and opportunities associated with climate change and disease migration, including impacts of malaria, dengue fever, and other vector-borne tropical diseases on non-tropical regions and populations.	n/a	Qualitative	Impact	
Governance	Corruption and Bribery	Description of legal and regulatory judgments, fines, and settlements (including \$ amount) related to bribery, corruption, or other unethical practices.	\$	Quantitative	Impact
	Operational Standards and Supply Chain Management	Number and type of FDA enforcement actions taken in response to violations of current good manufacturing practices (cGMP) including: product deemed adulterated, form 483s, suggested recall (Class I, II, III), Warning Letters, Border Alerts, license suspension or revocation, product seizure, Consent Decrees, criminal prosecution.	#	Quantitative	Impact
		Percentage of facilities and suppliers (by tier) participating in the Rx-360 International Pharmaceutical Supply Chain Consortium audit program, or equivalent third-party audit programs for integrity of supply chain and ingredients (e.g. APIs, chemical, raw material, excipients).	%	Quantitative	Innovation

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Pharmaceuticals

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		Discussion of management process for ensuring quality and patient safety during clinical trials conducted with third-party clinical research organizations (CROs), including process for obtaining informed consent and incentives offered to participants, by world region.	n/a	Qualitative	Impact
		Number of FDA Clinical Investigator Inspections of investigators used for clinical trials during the past year that resulted in: (1) Voluntary Action Indicated and (2) Official Action Indicated, as included on the Clinical Investigator Inspection List (CLIL).	#	Quantitative	Impact
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		Discussion of ongoing efforts to address orphan diseases.	n/a	Qualitative	Innovation
	Chronic Disease Prevention and Treatment	Revenue from drugs targeting obesity prevention and other drugs aimed at preventing chronic, non-communicable diseases (e.g. targeting high cholesterol, high blood pressure, or smoking cessation).	\$	Quantitative	Innovation
	Employee Recruitment, Development, and Retention	Description of talent recruitment and retention efforts for scientists and other research and development personnel, such as mentorship and career development programs, leadership training, or unique incentive structures.	n/a	Qualitative	Innovation
		Training and development expenditure per full time employee by: (1) expenditures for industry or professional qualification and advanced industry education; (2) all other.	\$	Quantitative	Innovation
		Employee turnover by voluntary and involuntary for: Executives/Senior Managers, Mid-level Managers, Professionals, All others (EEO-1 categories technicians, sales, admin support, service workers).	%	Quantitative	Impact
		Total Injury Rate (OSHA) - (Number of recordable injuries and illnesses /Hours worked)*200,000.	#	Quantitative	Impact
		DART rate (OSHA) - (Number of recordable injuries and illnesses resulting in days away from work, restricted work activity, or job transfers /Hours worked)*200,000.	#	Quantitative	Impact
		LAI (laboratory acquired infection) rate = LAIs per 1000 employees in human and animal diagnostic laboratories.	#	Quantitative	Impact
	Counterfeit Drugs	Description of methods and technologies used to maintain traceability of products throughout the supply chain (e.g. RFID, ePedigree, serialization).	n/a	Qualitative	Innovation
		Description of process for alerting customers and business partners of potential or known risks associated with counterfeit products.	n/a	Qualitative	Innovation
		Number (and description) of initiatives or actions that supported raids, seizure, arrests, and/or filing of criminal charges related to counterfeit products.	#	Quantitative	Innovation

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		Description of efforts to understand and monitor the effects of pharmaceutical products and their metabolites on ecological and human health throughout the product lifecycle (from manufacturing, use, and disposal).	n/a	Qualitative	Impact
	Resource Efficiency	Total energy consumption (gigajoules) - renewable energy consumption (gigajoules).	GJ	Quantitative	Impact
		Ratio of cost (\$ per gigajoule) of non-renewable energy to renewable energy.	n/a (\$)	Quantitative	Innovation
		Description of risks and opportunities associated with own greenhouse gas emissions.	n/a	Qualitative	Impact
		Water withdrawals in water-stressed regions - High or Extremely High Baseline Water Stress as defined by the WRI Water Risk Atlas.	m ³	Quantitative	Impact
		Water intensity (m ³ of production water per ton of product) in water-stressed regions - High or Extremely High Baseline Water Stress as defined by the WRI Water Risk Atlas.	m ³ /ton	Quantitative	Impact
Process Mass Intensity (PMI) = quantity of raw materials input (kg) / quantity of active pharmaceutical product (API) output (kg). Report overall PMI and for each of the following inputs: water, organic solvents, reactants, and other.	metric tons	Quantitative	Impact		
Disease Migration	Description of risks and opportunities associated with climate change and disease migration, including impacts of malaria, dengue fever, and other vector-borne tropical diseases on non-tropical regions and populations.	n/a	Qualitative	Impact	
Governance	Corruption and Bribery	Description of legal and regulatory judgments, fines, and settlements (including \$ amount) related to bribery, corruption, or other unethical practices.	\$	Quantitative	Impact
	Operational Standards and Supply Chain Management	Number and type of FDA enforcement actions taken in response to violations of current good manufacturing practices (cGMP) including: product deemed adulterated, form 483s, suggested recall (Class I, II, III), Warning Letters, Border Alerts, license suspension or revocation, product seizure, Consent Decrees, criminal prosecution.	#	Quantitative	Impact
		Percentage of facilities and suppliers (by tier) participating in the Rx-360 International Pharmaceutical Supply Chain Consortium audit program, or equivalent third-party audit programs for integrity of supply chain and ingredients (e.g. APIs, chemical, raw material, excipients).	%	Quantitative	Innovation

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Health Care Delivery

Category	ESG Issue	Key Performance Indicator (KPI)	UoM*	KPI Type	Impact / Innovation
Social Capital	Quality of Care and Patient Satisfaction	Hospitals Values Based Purchasing Total Performance Score, broken down by Clinical Process Domain score, Outcome Domain score, and Patient Experience Domain Score.	#	Quantitative	Impact
		Description of legal and regulatory judgments, fines, and settlements (including \$ amount) related to medical malpractice.	\$	Quantitative	Impact
		Number of serious reportable events (SREs) as defined by the National Quality Forum.	#	Quantitative	Impact
		Healthcare-acquired infections, as defined by the CDC's National Healthcare Safety Network, for: (1) CLABSI (central line-associated bloodstream infections) (2) SSIs (surgical site infections) (3) CAUTIs (catheter-associated urinary tract infections).	#	Quantitative	Impact
		Excess readmission ratio for pneumonia, acute myocardial infarction, and heart failure, as defined by the Centers for Medicare & Medicaid Services (CMS).	%	Quantitative	Impact
		Aggregate payments for excess readmissions as part of the Hospital Readmissions Reduction Program.	\$	Quantitative	Impact
		Access for Low Income and Uninsured Patients	Description of alternative pricing mechanisms or programs to extend services to the uninsured.	n/a	Qualitative
	Reimbursements received from Medicare, Medicaid, and Children's Health Insurance Program.		\$	Quantitative	Innovation
	Medicare bonus payments received by physicians for services provided in US Department of Health and Human Services designated Health Professional Shortage Areas (HPSA).		\$	Quantitative	Innovation
	Employee Recruitment, Development, and Retention	Number of incidents of employee infection in health care facilities.	#	Quantitative	Impact
		Aggregate turnover rate broken down by specialists, primary care physicians, physician's assistants, and nurse practitioners.	%	Quantitative	Impact
		Description of policies and programs of the following type aimed at attracting and retaining employees: mentorship programs, flexible scheduling, leadership development, other. Including participation or utilization rates for each type.	%	Quantitative	Innovation
	Preventative Care and Improved Outcomes	Description of programs designed to encourage patient wellness and preventative care.	n/a	Qualitative	Innovation
		Number of patients receiving well-visits during the past year. This includes receiving at least one no-cost preventative care service covered under the PPACA.	#	Quantitative	Innovation
	Pricing and Billing Transparency	Description of policies or initiatives to ensure that patients are adequately informed about price and alternatives before undergoing a procedure.	n/a	Qualitative	Innovation
		Describe how pricing information for services (inpatient, outpatient, physician office) is made publically available. Include the number of most common services for which there is publically available pricing information and the volume of total services that they represent.	#	Quantitative	Innovation

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Health Care Delivery (continued)

Category	ESG Issue	Key Performance Indicator (KPI)	UoM*	KPI Type	Impact / Innovation
Environment	Resource Efficiency	Total energy consumption (gigajoules) - renewable energy consumption (gigajoules).	GJ	Quantitative	Impact
		Ratio of cost (\$ per gigajoule) of non-renewable energy to renewable energy.	n/a (\$)	Quantitative	Innovation
		Description of risks and opportunities associated with own greenhouse gas emissions.	n/a	Qualitative	Impact
		Total weight of regulated medical waste (as defined by Medical Waste Tracking Act of 1988) generation and disposition (e.g. on-site incineration, landfill, Treatment/Storage/Disposal Facility, etc.).	metric tons	Quantitative	Impact
	Total weight of pharmaceutical waste generation and disposition (e.g. on-site incineration, landfill, Treatment/Storage/Disposal Facility, etc.) Breakdown: (1) RCRA waste; (2) non-RCRA hazardous waste; (3) solid waste.	metric tons	Quantitative	Impact	
Facilities Designed for Wellness	Description of efforts to construct or retrofit facilities that are designed to achieve patient wellness such as focusing on eliminating toxins (i.e. allergens, mutagens, carcinogens, endocrine disruptors), providing access to daylight, giving occupants control over environmental comfort, maintaining an adequate air change rate, etc. This may include following the Indoor Environmental Quality sections of the following guidelines: <ul style="list-style-type: none"> Green Guide for Health Care ASHRAE Green Healthcare Construction Statement LEED for Healthcare 	n/a	Qualitative	Innovation	
Governance	Fraud and Unnecessary Procedures	Description of legal and regulatory judgments, fines, and settlements (including \$ amount) related to Medicare and Medicaid Fraud under the False Claims Act.	\$	Quantitative	Impact
	Patient Privacy and Electronic Medical Records	Percentage of patient records that are electronic medical records (EMR) or electronic health records (EHR) and meet CDC definitions for "basic" or "fully functional".	%	Quantitative	Innovation
		Description of legal and regulatory judgments, fines, and settlements (including \$ amount) related to Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules violations or The Health Information Technology for Economic and Clinical Health (HITECH) Act violations.	\$	Quantitative	Impact

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Health Care Distributors

Category	ESG Issue	Key Performance Indicator (KPI)	UoM*	KPI Type	Impact/Innovation
Social Capital	Product Safety	Description of legal and regulatory judgments, fines, and settlements (including \$ amount) related to product safety.	\$	Quantitative	Impact
		Description of efforts to minimize health and safety risks of products sold including those related to toxicity/chemical safety (e.g. REACH substances of very high concern), high abuse potential (e.g. Schedule II controlled substances), or delivery (e.g. incorrect dispensing, mislabeling, transmission of disease through reuse of vials, etc.).	n/a	Qualitative	Innovation
	Counterfeit Drugs	Description of methods and technologies used to maintain traceability of products throughout the supply chain (e.g. RFID, ePedigree, serialization, etc.).	n/a	Qualitative	Innovation
		Description of due diligence process to qualify suppliers of drug products.	n/a	Qualitative	Innovation
		Description of process for alerting customers and business partners of potential or known risks associated with counterfeit products.	n/a	Qualitative	Innovation
Environmental Capital	Resource Efficiency	Total energy consumption (gigajoules) - renewable energy consumption (gigajoules).	GJ	Quantitative	Impact
		Ratio of cost (\$ per gigajoule) of non-renewable energy to renewable energy.	n/a (\$)	Quantitative	Innovation
		Description of risks and opportunities associated with own greenhouse gas emissions.	n/a	Qualitative	Impact
		Payload fuel economy = gallons per ton-miles.	gal/ton-miles	Quantitative	Impact
	Product Lifecycle Management	Description of involvement in efforts to reduce the environmental impact of logistics including involvement in the EPA SmartWay program.	n/a	Qualitative	Innovation
		Description of initiatives to reduce packaging waste (e.g. dematerialization, recycling, reusable totes, etc.).	n/a	Qualitative	Innovation
		Aggregate packaging to product weight ratio.	%	Quantitative	Impact
		Description of involvement in product and packaging take-back initiatives.	n/a	Qualitative	Innovation
Governance	Corruption and Bribery	Amount of product and/or packaging reclaimed through take-back initiatives.	\$	Quantitative	Innovation
		Description of efforts to minimize conflicts of interest and unethical business practices including mechanisms to ensure compliance.	n/a	Qualitative	Impact
		Description of legal and regulatory judgments, fines, and settlements (including \$ amount) related to corruption or bribery, including Foreign Corrupt Practices Act and False Claims Act violations.	\$	Quantitative	Impact

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Managed Care

Category	ESG Issue	Key Performance Indicator (KPI)	UoM*	KPI Type	Impact / Innovation
Environmental Capital	Integration of Environmental and Social Factors in Investment Management	Process of integrating ESG factors in investment management – whether conducted internally or externally – including research, investment decisions, engagement and exclusions and focusing on all major asset classes.	n/a	Qualitative	Innovation
		Amount of investment in companies that have a high climate risk exposure. These include, but are not limited to, the following industries: Transportation, Banking, Chemicals, Utilities, Healthcare Management Services, Multi-line Insurance, Non-renewable Energy, and Infrastructure & Real Estate.	\$	Quantitative	Impacts
		Amount of investments in companies developing innovative environmental or social solutions (e.g. low-carbon technologies, energy efficiency, renewables, social enterprise).	\$	Quantitative	Innovation
Social Capital	Access to Coverage	Medical Loss Ratio (MLR) = medical costs as percentage of premium revenue.	%	Quantitative	Impact
		Payments received from Medicare, Medicaid, and Children's Health Insurance Program.	\$	Quantitative	Innovation
		Revenue received from rental network activities.	\$	Quantitative	Impact
	Improved Outcomes	Percentage of enrollees in wellness programs by type: diet & nutrition, exercise, stress management & mental health, smoking or alcohol cessation, or other.	%	Quantitative	Innovation
		Total value of claims for health services not for the treatment of an illness or injury (preventative), as coded in ICD-10, CPT, or HCPCS classification systems.	\$	Quantitative	Innovation
		Number of customers receiving care from Accountable Care Organizations (as defined by CMS) or enrolled in other outcome-based provider reimbursement programs (e.g. pay for coordination, Patient-Centered Medical Home).	#	Quantitative	Innovation
	Plan Performance	Mean Medicare Advantage plan rating (1-5 stars) for each of the following plan types: HMO, local PPO, PFF, regional PPO.	1 to 5	Quantitative	Innovation
		Rebates paid due to non-compliance with Section 2718 of the PPACA for Medical Loss Ratio (i.e. the "80/20 Rule").	\$	Quantitative	Impact
		Percentage of proposed rate increases receiving "not unreasonable" designation from Health and Human Services (HHS) review or state review (where it is authorized to conduct the review).	%	Quantitative	Innovation
		Retention rates (voluntary termination).	%	Quantitative	Impact
		Overall rescission rate (involuntary termination) and rescission rate for highest-cost (top 5%) customers.	%	Quantitative	Impact
		Median claims processing time.	days	Quantitative	Impact
		Percentage of claims denial appeals made by customers that were upheld.	%	Quantitative	Impact
		Grievance rate per 1,000 enrollees.	#	Quantitative	Impact
	Pricing Transparency and Plan Literacy	Estimated losses due to fraud.	\$	Quantitative	Impact
JD Power & Associates members rating on "Information and Communication".		2 to 5	Quantitative	Innovation	
	Description of policies and practices related to clarity in pricing and coverage including health care literacy programs.	n/a	Qualitative	Innovation	

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Managed Care (continued)

Category	ESG Issue	Key Performance Indicator (KPI)	UoM*	KPI Type	Impact / Innovation
Governance	Provider Relationships	Median time period in days between the date the physician claim was received by the payer and the date the payer produced the first ERA (electronics remittance advice).	days	Quantitative	Impact
		Percentage of providers' healthcare delivery facilities designed to achieve patient wellness such as focusing on eliminating toxins (i.e. allergens, mutagens, carcinogens, endocrine disruptors), providing access to daylight, giving occupants control over environmental comfort, maintaining an adequate air change rate, etc. This may include following the Indoor Environmental Quality sections of the following guidelines: <ul style="list-style-type: none"> Green Guide for Health Care ASHRAE Green Healthcare Construction Statement LEED for Healthcare. 	ft ²	Quantitative	Innovation
		Description of claim payment procedures and use of medical necessity guidelines.	n/a	Qualitative	Innovation
	Customer Privacy and Technology Standards	Description of legal and regulatory judgments, fines, and settlements (including \$ amount) related to Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules violations or The Health Information Technology for Economic and Clinical Health (HITECH) Act violations.	\$	Quantitative	Impact
		Number of cyber security incidents that resulted in actual outcomes of a business process deviating from the expected outcomes for confidentiality, integrity, and availability due to deficiencies or failures of people, process, or technology.	#	Quantitative	Impact

* UoM = Unit of Measure

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Any comments and suggestions will be considered but are not guaranteed to be incorporated into the final SASB Standards. –



Medical Equipment and Supplies

Category	ESG Issue	Key Performance Indicator (KPI)	UoM*	KPI Type	Impact/Innovation
Social Capital	Product Safety	List of products recalled with associated revenue in the 12-month period preceding the recall.	\$	Quantitative	Impact
		Description of legal and regulatory judgments, fines, and settlements (including \$ amount) related to product safety.	\$	Quantitative	Impact
		Fatalities related to products as reported in the FDA Adverse Event Reporting System.	#	Quantitative	Impact
	Ethical Marketing	Description of legal and regulatory judgments, fines, and settlements (including \$ amount) related to off-label use of products.	\$	Quantitative	Impact
		Description of code of ethics governing off-label use of products including mechanisms to ensure compliance.	n/a	Qualitative	Innovation
	Affordability, Access, and Fair Pricing	Ratio of weighted average rate of net price increases (for all products) to annual increase in U.S. Consumer Price Index.	\$	Quantitative	Impact
Manufacturer discloses average and median price information for each product to customers or their agents (e.g. group purchasing organizations or consultants).		y/n	Qualitative	Innovation	
Environmental Capital	Resource Efficiency	Total energy consumption (gigajoules) - renewable energy consumption (gigajoules).	GJ	Quantitative	Impact
		Ratio of cost (\$ per gigajoule) of non-renewable energy to renewable energy.	n/a (\$)	Quantitative	Innovation
		Description of risks and opportunities associated with own greenhouse gas emissions.	n/a	Qualitative	Impact
		Discussion of products that contain raw materials facing resource scarcity or availability constraints.	n/a	Qualitative	Impact
	Product Lifecycle Management	Description and associated revenue of products with environmental considerations made at product lifecycle stages such as design, procurement, manufacturing, distribution, use, and end-of-life. Efforts may include elimination of toxics, use of recycled materials, reduced packaging, design for consolidated shipping, low energy consumption products, design for take back, labeling for recycling, etc.	\$	Quantitative	Innovation
		Description of Extended Producer Responsibility (EPR) initiatives to promote manufacturer take-back, reuse, or adequate dispose at the end of the lifecycle.	n/a	Qualitative	Innovation
		Original sales value of product taken back, reused, or donated through Extended Producer Responsibility (EPR) initiatives.	\$	Quantitative	Innovation
Governance	Corruption and Bribery	Description of legal and regulatory judgments, fines, and settlements (including \$ amount) related to violations of the Foreign Corrupt Practices Act.	\$	Quantitative	Impact
		Description of legal and regulatory judgments, fines, and settlements (including \$ amount) related to providing kickbacks to physicians.	\$	Quantitative	Impact
		Description of code of ethics governing interactions with healthcare professionals including mechanisms to ensure employee compliance.	n/a	Qualitative	Innovation
	Operational Standards and Supply Chain Management	Number and type of FDA enforcement actions taken in response to violations of current good manufacturing practices (cGMP) including: product deemed adulterated, form 483s, suggested recall (Class I, II, III), Warning Letters, Border Alerts, license suspension or revocation, product seizure, Consent Decrees, criminal prosecution.	#	Quantitative	Impact
		% of facilities and suppliers (by tier) participating in third-party audit programs for integrity of supply chain and products (e.g. materials, devices, packaging, etc.).	%	Quantitative	Innovation

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EXPOSURE DRAFT FOR PUBLIC COMMENT

#HC0201

		Description of efforts to maintain traceability within the supply chain, particularly with respect to wholesalers, re-packagers, contract distributors.	n/a	Qualitative	Innovation
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* UoM = Unit of Measure

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