What you need to know about the Health Care Standards for the pharmaceuticals and biotechnology industries by the Sustainability Accounting Standards Board [SASB] and how EY can help
This thought leadership piece provides key details about the recently released SASB Health Care Standards and describes the services that EY can provide to companies in the pharmaceuticals and biotechnology industries to assist with identifying and reporting on the material sustainability topics affecting their business. Subsequent thought leadership pieces will focus on the standards for medical equipment & supplies, health care delivery, health care distributors and managed care industries.

- The Health Care Standards identify the sustainability topics that are material to the pharmaceuticals and biotechnology industries and also provide guidance on accounting metrics that can be utilized by these industries with an aim of achieving standardized reporting. Specifically, the Health Care Standards provide the following information:
  - Disclosure guidance: the sustainability topics that SASB has identified as being material to the biotechnology and pharmaceuticals industries
  - Accounting standards: standardized metrics to account for the material sustainability topics specified in the disclosure guidance when reporting to the United States Securities and Exchange Commission (SEC) in annual Form 10-K filings (Form 20-F for international companies) and other relevant periodic filings (Form 10-Q, Form 8-K, Form S-1 and Form S-3), as applicable
- The development process for the standards involved vetting of the material sustainability topics and metrics by an industry working group (IWG), which, as stated by SASB, consisted of “publicly traded companies with more than $800 billion market cap, and investment firms with more than $952 billion in assets under management.”
- The standards are currently provisional in nature until ratification by an external consensus body, which is set to occur in 2015 after SASB releases all its standards that are currently in the pipeline (SASB plans on releasing nine additional sector standards).
- It is not mandatory for companies in the pharmaceuticals and biotechnology industries to disclose information on the material sustainability topics affecting them in conformity with the SASB standards.
- The standards have been designed in alignment with the SEC’s definition of materiality, and the SEC has been briefed about the standards during their development process.

The following are the sustainability topics material to the pharmaceuticals and biotechnology industries, as identified by SASB:

- Access to medicines
- Drug safety and side effects
- Safety of clinical trial participants
- Affordability and fair pricing
- Ethical marketing
- Employee recruitment, development and retention
- Employee health and safety
- Counterfeit drugs
- Energy, water, and waste efficiency
- Corruption and bribery
- Manufacturing and supply chain quality management
Introduction to SASB

SASB, a 501 (c) non-profit organization established in 2011 and accredited for the production of sustainability accounting standards by the American National Standards Institute (ANSI) released its Health Care Standards on 31 July 2013. SASB’s goal is to design common standards for sustainability disclosures that will ultimately be included in mandatory filings to the SEC. The Health Care Standards are the first set of standards released by SASB, and the organization is in the process of developing an additional nine standards comprising more than 80 industries.1

Standards development process

Stage 1 – sector research: research is conducted on the environmental, social and governance (ESG) issues affecting the sector for which the standards are being developed. Information gathered from the research process is compiled into industry briefs.

Stage 2 – vetting process: the initial set of issues and metrics compiled based on the research conducted in stage 1 undergoes a vetting process by the IWG,2 which for the Health Care Standards, according to SASB consisted of “publicly traded companies with a more than $800 billion market cap, and investment firms with more than $952 billion in assets under management.”

Stage 3 – standards development: the vetted issues and metrics are published as “public notice of material issues” and are reviewed by the Standards Council,3 which also reviews the standards development process leading up to that stage. At this point, the SEC is briefed about the standards under development.

Stage 4 – public comment: the standards are released for public comment after which it undergoes further review by the Standards Council and is then made publically available.

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Source: SASB

1 In addition to the Health Care Sector Standards, the other standards being developed by SASB are for the following sectors: financials (the next standard being released), technology and communication, non-renewable resources, transportation, services, resource transformation, consumption, renewable resources and alternative energy, and infrastructure.

2 For a full list of SASB’s IWG members for the Health Care Standards, please refer to the following link: http://www.sasb.org/sectors/health-care/

3 For a full list of the members of SASB’s Standards Council, please refer to the following link: http://www.sasb.org/sasb/standards-council/
Overview of the Health Care Standards

The SASB Health Care Standards provide the following information:

- **Disclosure guidance:** the material sustainability topics relevant to the industry under consideration
- **Accounting standards:** standardized metrics to account for the material sustainability topics specified in the disclosure guidance

*Please refer to the table on pages 5–8 for the accounting metrics for the pharmaceuticals and biotechnology industries.*

Within the Form 10-K, the standards recommend that companies disclose information on their material sustainability topics in the “Management’s Discussion and Analysis” section under a separate subsection titled “Sustainability Accounting Standards Disclosure.” According to SASB, other sections of the Form 10-K that can be leveraged for disclosure include the sections on the company’s description of business, legal proceedings, risk factors affecting investment in the company and the sections containing additional information related to materiality as mandated by the Securities Act Rule 408 and Exchange Rule 12b-20.

With respect to the scope of disclosure, SASB recommends that companies disclose information on material sustainability topics affecting itself and entities over which it has controlling interest. Further, SASB also recommends, “that for consolidated entities, disclosures be made, and accounting metrics calculated, for the whole entity, regardless of the size of the minority interest” and “information from unconsolidated entities not be included in the computation of SASB accounting metrics. A registrant should disclose, however, information about unconsolidated entities to the extent that such registrant considers the information necessary for investors to understand its performance with respect to sustainability issues.”

A number of recommendations and mandatory requirements (to be followed for a company to claim alignment with the SASB standards) related to reporting and assurance are also provided in the SASB Health Care Standards.4

Users of the Health Care Standards

The Health Care Standards are mainly aimed to be utilized by publicly traded companies when filing their Form 10-K, or Form 20-F in the case of international companies. Health care companies can also utilize the Health Care Standards to guide disclosure on materiality in their Form 10-Q, Form 8-K, Form S-1 and Form S-3.

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4 SASB provides guidance on the normalization of accounting metrics, reporting in International System of Units (SI Units), disclosure on uncertainty, disclosure on the nature and basis of any estimates used, the timing of disclosure and the use of a high level of assurance, among other topics.
SASB definition of materiality: SASB adheres to the U.S. Supreme Court definition of materiality, defined as “presenting a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the ‘total mix’ of information made available.” [U.S. Supreme Court definition, (TSC Indus. V. Northway, Inc., 426 U.S. 438 (1976) and Basic v. Levinson, 485 U.S. 224 (1988)]

SASB definition of sustainability: “In the context of SASB standards, sustainability refers to environmental, social and governance (ESG) factors that have the potential to affect corporations’ long-term value creation and are in the interest of investors and the public.”

Provisional and voluntary nature of the Health Care Standards

It should be noted that the Health Care Standards are provisional in nature and according to SASB will remain provisional until “the full set of standards (for 80+ industries) is reviewed and ratified by an external consensus body, such as that required by the American National Standards Institute (ANSI).” The full set of standards is scheduled to be ratified in 2015.

It is not mandatory for companies in the health care sector to disclose information on their material sustainability topics in alignment with the Health Care Standards, and the standards themselves have not been endorsed by the SEC. However, the Health Care Standards have been designed in alignment with the requirements specified by the SEC for the materiality content in its mandatory filings.

Next steps

SASB will be organizing a corporate pilot program for the Health Care Standards in the first quarter of 2014. Companies that volunteer to be a part of the corporate pilot program will have subject matter experts assisting them with the identification and reporting of material sustainability topics specific to their business. Additional information about the Health Care Standards pilot program will be provided by SASB in September.
Description and accounting metrics for material sustainability topics in the pharmaceuticals and biotechnology industries

SASB identifies the following sustainability topics as being material to the pharmaceuticals and biotechnology industries:

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<th>Material sustainability topics</th>
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| Access to Medicines | Pharmaceutical and biotechnology companies play an important role in providing access to the industry’s products around the world. Firms can develop pricing frameworks that account for differing levels of economic development and health care needs across various countries. Further, the industry can target priority diseases in developing countries. A strategic approach to access to medicines can yield opportunities for growth, innovation, and unique partnerships, which can enhance shareholder value. | • Description of initiatives to promote access to health care products in priority countries as defined by the Access to Medicine Index.  
• List of products on the WHO List of Prequalified Medicinal Products as part of its Prequalification of Medicines Programme (PQP). |

Drug Safety and Side Effects | 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. Pharmaceutical and biotechnology firms that limit safety issues will be better positioned to protect shareholder value. In addition, concern over the abuse or resale of certain medications has led to mandated take-back programs. Firms that are able to successfully engage in these programs will likely limit future liabilities. | • List of products listed in the FDA’s MedWatch Safety Alerts for Human Medical Products (Drugs and Therapeutic Biological Products) database, including those products with Potential Signals of Serious Risks or that have New Safety Information identified by the FDA Adverse Event Reporting System (FAERS).  
• Number of fatalities associated with products as reported in the FDA Adverse Event Reporting System.  
• List of products recalled.  
• Description of product stewardship initiatives to promote take-back and redistribution or safe permanent disposal of unused product at the end of its lifecycle. Where applicable: (1) amount of direct funding for such initiatives and (2) amount of product (by weight) accepted for take-back, reuse, or disposal. |
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| Safety of Clinical Trial Participants | Clinical trials are an essential component of the approval process for pharmaceutical and biotechnology products. The safety of clinical trial participants reflects a company’s ability to successfully bring a product to market. Oversight of these trials is of increasing importance as the number of clinical trials conducted by third party contract research organizations in emerging countries continues to rise. Pharmaceutical and biotechnology companies that effectively manage clinical trials will be positioned to enhance shareholder value through the revenue associated with new products. | - Discussion, by world region, of management process for ensuring quality and patient safety during clinical trials, including those conducted with third-party clinical research organizations (CROs). Description of processes for obtaining informed consent, of incentives offered to participants, and of any clinical trials terminated due to failure to follow good clinical practice standards.  
- Number of FDA Clinical Investigator Inspections of investigators used for clinical trials during the past year that resulted in: (1) Voluntary Action Indicated (VAI) and (2) Official Action Indicated (OAI).  
- Description of legal and regulatory fines and settlements associated with clinical trials in World Bank Low-income and Lowermiddle-income Countries (LICs and LMICs) and UN HDI Medium-High Development Countries (MHDCs) that are not captured by the World Bank's LIC or LMIC rankings. Dollar amount of fines and settlements and a description of corrective actions implemented in response to events. |
| Affordability and Fair Pricing | Legislative emphasis in the U.S. and abroad on health care cost containment and increased access will continue to place downward pricing pressures on pharmaceutical and biotechnology products. As a result, companies that have relied on contractual advantages and reverse payments to protect profits may be challenged to enhance value as efforts to reduce costs gain traction. 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. | - Number of settlements of Abbreviated New Drug Application (ANDA) litigation that involved payments and/or provisions to delay bringing an authorized generic product to market for a defined time period.  
- Ratio of weighted average rate of net price increases (for all products) to the annual increase in the U.S. Consumer Price Index. |
| Ethical Marketing | Pharmaceutical and biotechnology companies face challenges associated with the marketing of specific products. Consumer-directed advertisements for prescription drugs in the U.S. provide opportunities for increasing market share. However, challenges also arise from the potential for marketing off-label uses. Corporate disclosure of legal and regulatory fines and the codes of ethics that govern interactions with health professionals will allow shareholders to monitor performance in this area. | - Description of legal and regulatory fines and settlements associated with false marketing claims, including Federal Food, Drug, and Cosmetic Act violations for off-label marketing prosecuted under the False Claims Act. Dollar amount of fines and settlements and a description of corrective actions implemented in response to events.  
- Description of code of ethics governing promotion of off-label use of products, including mechanisms to ensure compliance. |
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| **Employee Recruitment, Development and Retention** | Pharmaceutical and biotechnology companies face intense competition for employees. The industry relies on highly skilled employees to develop new products, conduct clinical trials, manage government regulations, and commercialize new products. Firms that are able to attract and retain employees in light of a limited talent pool will be better positioned to protect and enhance shareholder value. | • Description of talent recruitment and retention efforts for scientists and other research and development (R&D) personnel, such as mentorship and career development programs, leadership training, or unique incentive structures.  
• Training and development expenditures per full time employee by: (1) expenditures for industry or professional qualification and advanced industry education; (2) all other.  
• 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). |
| **Employee Health and Safety** | The pharmaceutical and biotechnology industries are subject to federal, state, and local regulations regarding workplace safety. Companies must ensure compliance and in many cases exceed current regulations to protect the health and safety of employees who are exposed to hazardous materials, chemicals, viruses, and other essential inputs. A failure to manage these risks could result in negative material impacts through litigation, fines, and penalties. | • Total Injury Rate - (Number of recordable injuries and illnesses / Hours Worked)*200,000.  
• Days Away, Restricted, or Transferred (DART) rate - (Number of recordable injuries and illnesses resulting in days away from work, restricted work activity, or job transfers / Hours Worked)*200,000.  
• Laboratory-acquired infection (LAI) rate - LAIs per 1000 employees in human and animal diagnostic laboratories. |
| **Counterfeit Drugs** | The World Health Organization estimates that the global market for counterfeit drugs has reached $431 billion, representing one percent of the U.S.’s supply, and 10-15 percent of the world’s pharmaceuticals market. This issue presents a significant health and safety risk to consumers with an estimated 100,000 annual deaths attributed to substandard or counterfeit drugs worldwide. Pharmaceutical and biotechnology companies subsequently face material risks associated with the potential loss of public confidence and reduced revenue. | • Description of methods and technologies used to maintain traceability of products throughout the supply chain and prevent counterfeiting.  
• Description of process for alerting end customers and business partners of potential or known risks associated with counterfeit products.  
• Number (and description) of actions that led to raids, seizure, arrests, and/or filing of criminal charges related to counterfeit products. |
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| Energy, Water and Waste Efficiency | The manufacturing of pharmaceutical and biotechnology products requires the use of energy, water, and material inputs, in addition to the creation of waste. As concerns over climate change and dwindling natural resources continue to impact pricing, pharmaceutical and biotechnology companies will be exposed to fluctuations in costs of these key inputs. Firms that are able to improve manufacturing efficiencies and limit dependence on finite resources are likely to enhance shareholder value. | - Total annual energy consumed (gigajoules) and percentage renewable (e.g., wind, biomass, solar).  
- Total water withdrawals and percentage in water-stressed regions - High or Extremely High Baseline Water Stress as defined by the WRI Water Risk Atlas; percentage of process water recycled.  
- Overall Process Mass Intensity (PMI) and PMI broken down for water and organic solvents, where PMI = quantity of raw materials input (kg) / quantity of active pharmaceutical product (API) output (kg).  
- Amount of waste (metric tons); percentage that is recycled, incinerated (including for energy recovery), and landfilled. |
| Corruption and Bribery       | Pharmaceutical and biotechnology firms are subject to various state, federal, and international laws pertaining to health care fraud and abuse. Anti-kickback laws and the U.S. Foreign Corrupt Practices Act generally prohibit companies from making payments for the purpose of obtaining or retaining business. The ability of companies to ensure compliance both in the U.S. and abroad is likely to have material implications. | - Description of legal and regulatory fines and settlements associated with bribery, corruption, or other unethical business practices, including violations of the Foreign Corrupt Practices Act and those associated with providing kickbacks to physicians. Dollar amount of fines and settlements and a description of corrective actions implemented in response to events.  
- Description of code of ethics governing interactions with health care professionals, including mechanisms to ensure employee compliance. |
| Manufacturing and Supply Chain Quality Management | Manufacturing and supply chain quality is essential to protecting consumer health and corporate value. Pharmaceutical and biotechnology 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. | - Description 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. Description of corrective actions implemented in response to actions.  
- Percentage of facilities and Tier I suppliers 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, recipients, etc.). |

*Table consolidated from SASB Health Care Standards for the pharmaceuticals and biotechnology industries*
How EY can help

The following is a list of services that EY can provide to pharmaceutical and biotechnology companies to guide them through the process of identifying sustainability topics material to their business, reporting on these topics and addressing the potential risks faced by their business:

- **Industry benchmarking**: EY’s Climate Change and Sustainability Services (CCaSS) team can provide key insights on sustainability best practices in the pharmaceutical and biotechnology industries based on research and industry experience, including benchmarking the 11 material topics in the Health Care Standards.

- **Gap assessment and recommendations**: CCaSS can provide a gap assessment against industry best practices and current sustainability initiatives in place, with an aim to identify gaps for improvement and provide recommendations on addressing these gaps.

- **Identification of material sustainability topics in alignment with the requirements specified in the SASB Health Care Standards**: CCaSS can assist pharmaceutical and biotechnology companies seeking to identify the material sustainability topics specific to them. We can assist companies with evaluating whether reporting in their annual or periodic filings to the SEC in alignment with the guidance provided in the Health Care Standards is right for them.

- **Environment, health and safety (EHS) assessments**: we can assist clients with managing EHS and sustainability risks, identifying and generating cost savings and implementing process improvements.

- **Assurance readiness**: SASB's hope is that registrants will report on sustainability metrics with the same rigor, accuracy and responsibility as all other information in the SEC filings. SASB is recommending that registrants use a higher level of assurance (attestation), such as the American Institute of Certified Public Accountants’ AT Section 701. We can assist clients on their assurance journey by first providing assurance readiness over individual material sustainability topics identified by pharmaceutical and biotechnology companies to evaluate the associated processes and controls and in doing so increase internal confidence and reduce the risk of misstatement.

- **Assurance**: when clients are ready for independent assurance, we can also provide assurance over individual material sustainability topics identified by pharmaceutical and biotechnology companies to add an additional level of credibility to reports that resonate with investors, non-governmental organizations (NGOs) and other stakeholders.
Our point of view

Some of our published insights include:

Demystifying sustainability risk
Sustainability's evolving role in business has created new risks. See how the COSO Framework can help your organization's risk management.

Six growing trends in corporate sustainability
As shareholders speak up and companies begin connecting risk management and corporate sustainability, environmental issues become more prominent on company agendas.

Conflict minerals
What you need to know about the new disclosure and reporting requirements and how EY can help

How today's investors are framing conversations on corporate sustainability
Investors with long-standing interests in environmental and social (E+S) topics are having an increasing impact on how companies address corporate sustainability.

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