IFPW FOCUS
A Bi-Weekly Pharmaceutical Industry Newsletter
Celebrating Our 30th Year in Publication!
Vol 31 | No. 13
July 6, 2023

Ten Things to Know About the First ISSB Standards

(Source: A Press Release from the International Financial Reporting Standards)

ISSB has issued its inaugural International Financial Reporting Standards' *Sustainability Disclosure Standards*, designed to provide a global baseline of sustainability-related disclosures for the capital markets.

Better information leads to better economic decisions. IFRS S1 requires companies to communicate the sustainability-risks and opportunities they face over the short, medium and the long term. The requirements are designed to ensure that companies provide investors' information relevant to decision-making. IFRS S2 sets out specific climate-related disclosures and is designed to be used with IFRS S1. Both Standards are based on recommendations of the Task Force on Climated-related Financial Disclosures (TCFD).

Issuing these Standards is just the starting point. The ISSB is consulting on future priorities to help determine what comes next and is accepting feedback before the consultation closes on September 1, 2023.

Here are the 10 things you need to know about the ISSB's new standards:

1. *Global disclosure standards.* ISSB Standards allow companies and investors to standardize on a single, global baseline of sustainability disclosure for the capital markets, with any additional jurisdictional requirements being built on top of this global baseline.

2. *International support.* The ISSB's work has received strong support from investors, companies, policy makers, market regulators and others from around the world, including the International Organization of Securities Commissions (IOSCO), the Financial Stability Board, the G20, and the G7 leaders.

3. *Disclosure of decision-useful material information.* Focusing exclusively on capital markets means that ISSB Standards only require information that is material, proportionate and decision-useful to investors. Moreover, by beginning with climate, companies can phase-in their sustainability disclosures.

4. *Building on and consolidating existing initiatives.* IFRS S1 and IFRS S2 are built on and consolidate the TCFD recommendations, SASB Standards, CDSB Framework, Integrated Reporting Framework and World Economic Forum metrics to streamline sustainability disclosures. Consolidation will help companies to benefit from their investments they have already made in sustainability disclosures while reducing the "alphabet soup" of sustainability disclosures.

5. *Reducing duplicative report.* The baseline approach provides a way to achieve global comparability for financial markets and allow jurisdictions to further develop additional requirements if needed to meet public policy or broader

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In Brief...

- **Walgreens Boots Alliance** reported third-quarter sales of US$27.9 billion, an increase of 4.4% year-over-year. CEO *Rosalind Brewer* said, "WBA achieved 8.9% constant currency sales growth in the third quarter despite a challenging operating environment. Consumers continue to appreciate the value, convenience and range of services provided by Walgreens and Boots. However, significantly lower demand for COVID-related services, a more cautious and value-driven consumer and a recently weaker respiratory season created margin pressures in the quarter."

- **McKesson Corporation** has launched a curated private brand of over-the-counter (OTC) health and wellness products to meet the growing and changing needs of consumers. Its new brand, **Foster & Thrive**, unifies McKesson's private brand portfolio by consolidating **Health Mart** and **Sunmark** branded OTC products to offer greater availability through increased production and efficiencies to help meet evolving patient needs and growing demand, the company said. The company has created four product categories – acute care, diagnostic care, everyday care and preventative care. McKesson's goal is to seamlessly transition Health Mart and Sunmark items to the new Foster & Thrive brand by category beginning in July and continuing through October of 2024.

- **Blackstone** will sell its controlling stake in South Korean pharmaceutical wholesaler **Geo-Young** in a deal estimated at US$1.4 billion. The private equity firm acquired a 71% stake in Geo-Young in 2019 at an enterprise value of US$845.8 million. Geo-Young is South Korea's largest medicine wholesaler by revenue, controlling

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Japan's MHLW Panel Discusses Six Risks to Drug Supplies

(Source: An article by Yoshinori Sagehashi for Pharma Japan)

A council of the Ministry of Health, Labor, and Welfare (MHLW) discussed six main risks and challenges to drug supplies presented by the ministry, with members stressing the need for "industry consolidation" and "surplus inventories".

The MHLW solicited open discussion from members at the day's eighth meeting of the council on stable drug supplies based on the six main supply risks and challenges identified. The ministry will review the panel's opinions and decide specific themes to be discussed in greater detail going forward.

The first risk/challenge is the excessive reliance on a few companies in particular countries with low labor and raw material costs for the production of raw materials and active pharmaceutical ingredients (APIs). When supplies from these

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Ten Things (cont.)...

stakeholder needs. This approach helps to reduce duplicative reporting for companies subject to multiple jurisdictional requirements.

6. *Helping companies communicate worldwide cost effectively.* ISSB Standards have been designed to provide reliable information to investors; helping companies to communicate how they identify and manage the sustainability-related risks and opportunities they face over the short, medium, and longer term.

7. *Connections with financial statements.* The information required by the ISSB Standards is designed to be provided alongside financial statements as part of the same reporting package. ISSB Standards have been developed to work with any accounting requirement, but they are built on the concepts underpinning IFRS Accounting Standards, already required for use by more than 140 jurisdictions.

8. *Developed through rigorous consultation.* ISSB Standards have been developed using the same inclusive, transparent due process used to develop IFRS Accounting Standards – with more than 1,400 responses to the ISSB's proposals. All ISSB papers, feedback, and technical decision-making are available to view online.

9. *Interoperability with broader sustainability reporting.* The ISSB's partnership with the Global Reporting Initiative enables the ISSB to build its requirements to be interoperable with GRI Standards, helping to reduce the disclosure burden for companies using both ISSB and GRI Standards for reporting.

10. *A partnership for capacity building.* The ISSB's responsibilities do not stop at standard setting. At COP27, the ISSB announced plans for a capacity building partnership program, helping to establish the necessary resources for high quality, consistent reporting across developed emerging economies.

Together, these inaugural standards and the ISSB's capacity building program will help build trust, confidence and much-needed global comparability to the sustainability disclosure landscape.

Japan's (cont.)...

companies are cut off, the re-supply of drugs becomes difficult. Political and social situations in particular countries can also put the stable supply of drugs at risk. Manufacturing constraints can hinder the entry of new suppliers as well.

The second is the fact that changes in drug manufacturing costs cannot be reflected in sales prices. Exchange rate fluctuations, inflation, increased labor costs among contract manufacturers, and steep hikes in transportation fuel costs are all major threats. According to MHLW, 28% of drugs are now unprofitable, while 24% are only marginally profitable.

The third main risk is the harmful impact of particular regulations in Japan. If Japan is not an important export destination, overseas suppliers could refuse to deal with unique regulations in Japan, put off responding to additional requests, or demand higher prices. In addition, it could result in delayed shipments.

The fourth is the growing complexity of supply chain management for drugmakers. Bigger product lineups and more suppliers make it tougher, particularly for generic makers, to manage supply chains and handle the additional information involved. The globalization of supply chains for raw materials and APIs makes it harder to ascertain the situation of business partners and respond to problems in a timely manner.

The fifth main risk to drug supplies is the inability of drug makers to obtain up-to-date information on the supplies of raw materials used in their drugs. Inability to obtain raw materials in a stable manner can lead to increased demand for substitute drugs and cause supply panics.

The sixth is the low profitability of generic and long-listed products which makes it harder to invest additional resources in manufacturing. Some companies try to fulfill their social obligation to supply drugs in a stable manner, but others seek only high profits. In addition, a MHLW notification that provides multiple stable supply requirements for generics only requires companies to supply their products for five years.

MHLW plans to set up a working group that will report to the council. In April of this year, the Federation of the Pharmaceutical Manufacturers' Association of Japan (FPMAJ) began surveying the statuses of drug supplies on a monthly rather than quarterly basis. Against this backdrop, the working group will discuss ways to collect drug supply information more effectively and provide it to healthcare professionals.

The working group will sort out challenges pointed out by the council members in past discussions. It will submit its interim report at the council's ninth meeting in November or December and its final report at the 10th meeting scheduled for later this fiscal year, which will end in March of 2024.

In Brief (cont.)

approximately 80% of the domestic medicine and medical device distribution market.

- **Sandoz** is launching the *Act4Biosimilars Action Plan*, which is part of the *Act4Biosimilars Initiative*, founded by Sandoz and launched in 2022. The initiative aims to increase global biosimilar adoption by at least 30 percentage points in more than 30 countries by 2030. The Act4biosimilars Action Plan highlights some of the most critical challenges preventing patient access to biosimilar medicines, as well as actionable steps to accelerate adoption by overcoming those challenges. The Action Plan will be complemented by a series of reports which will provide an analysis of the key challenges by region.
- The **U.S. Food and Drug Administration** has declined to approve **Amneal Pharmaceuticals'** drug designed to help control symptoms in Parkinson's disease patients for a longer duration, citing inadequate safety data. The agency had requested additional data as it was not convinced about the safety of one of the ingredients, *carbidopa*, even though some studies have demonstrated the safety of the other component, *levodopa*, the company said. The drug is a new formulation of *carbidopa-levodopa*, the standard of care for Parkinson's, and is designed to allow it to remain in the small intestine for a longer period, helping it in its consistent absorption.

(Sources: Company Press Releases, Drug Store News, FiercePharma, PharmaVoice, and Reuters)