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Nearly 700 Drugs Found to be Unprofitable in Japan Due to Inflation

(Source: A staff article in Pharma Japan)

Despite Japan's ambitions for more secured supplies, 696 drugs from 94 companies have been found to be unprofitable as a result of such factors as surging prices and the fluctuating yen, according to a health ministry survey.

The Ministry of Health, Labor and Welfare (MHLW) presented the survey results to a panel of academic experts on comprehensive pharmaceutical measures at a recent meeting. The poll was conducted via the Federation of Pharmaceutical Manufacturers' Associations of Japan between September 8th and September 30th of 2022.

In the survey, drug manufacturers were asked to select medicines that applied to all of the following three criteria: 1) items that have become unprofitable on the back of soaring prices and yen volatility, 2) essential medicines, "stable supply medicines" (Categories A to C), or medicines that are deemed to be medically essential based on requests from academic societies or for other reasons, and 3) items that are prone to cause supply disruptions due to such factors as holding a large market share.

A total of 696 such products were identified. Of this number, 209 were essential medicines while 64 were classified as Category A (top priority), 18 under Category B (priority) and 140 were categorized as other medicines. Looking at the breakdown of price hikes causing such unprofitability (for various reasons), the top category was "API, excipient and other raw material costs" with 516 applicable products, followed by "containers and packaging costs" with 454 products, and "manufacturing expenses (energy costs) for 450 products. Classified by dosage form, 172 were oral, 353 were injectable, and 171 were topical in nature.

The MHLW also presented results of another survey conducted by the Japan Generic Medicines Association (JGA), which showed that over 30% of all generics covered were yielding virtually no profit. The results covered JGA member companies' production costs as a percentage of revenue as of October 14th. The trade group had submitted the data in response to a request made by the panel at their previous meeting on October 12th asking for details on generic manufacturing costs.

Of the 37 member companies, the 30 that submitted responses covered a total of 5,378 products on the NHI price list, excluding those that are subject to transitional measures. Of this, 1,632 products (30.3%) had manufacturing costs exceeding 80% of their NHI prices, making them basically unprofitable.

The number of such products with 80%-plus cost rates was 28 in stable supply medicines Category A (37.8% of the total of 1,741). Among the essential medicines (a total of 186) 36 items (19.4%) were found to have a manufacturing cost ratio above 80%.

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In Brief...

- **McKesson Corporation** has opened a new state-of-the-art pharmaceutical distribution center in Jeffersonville, Ohio – a location that is centrally located between Cincinnati and Columbus. The new facility will distribute pharmaceutical, over-the-counter (OTC), and home healthcare products as well as consumer packaged goods to customers across Ohio, Indiana, Kentucky, Michigan, Pennsylvania and West Virginia. The new facility features cutting edge sustainability and automation technology that support a safe and productive work environment, according to the company.
- **MWI Animal Health U.K.**, a division of **AmerisourceBergen Corporation**, launched *MWI Pet*, a new technology offering designed to assist veterinary practices and increase engagement with clients while reducing administrative burdens on their teams. MWI Pet enables an efficient digital contact experience between veterinary practices and pet owners, and seamlessly integrates with the *Merlin* practice management system (a cloud-based technology which offers integrated tools and applications to support key workflows.)
- **Walgreens Boots Alliance** reported 4th quarter and fiscal year results, with quarterly sales of US$32.4 billion, representing a decrease of 5.2% year-over-year (3.2% on a constant currency basis.) Fourth quarter operating losses from continuing operations were US$822 million compared to operating income of US$910 million in the year-ago quarter. The operating loss reflects a US$783 million non-cash impairment charge related to intangible assets in Boots U.K. and higher costs related to the *Transformational Cost Management Program*. Separately, returning for its 9th season, the *Walgreens Flu Index* for 2022-2023 shows that, to date, overall flu activity is more than 10 times higher

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SAVE THE DATE
for
IFPW's CEO Roundtable
MAY 3-4, 2023
The Corinthia Hotel in London
Registration to open February 1st
Attendees are encouraged to register early as the meeting coincides that week with the Coronation of King Charles III (on May 6th). For more information, contact ***Christina Tucker*** *at* ***c.tucker@ifpw.com***

Nearly 700 Drugs (cont.)...

Panel member Hiroyuki Sakamaki, a professor at Kanagawa University of Human Services, said at the meeting "I understood that there are many products with rising sales cost ratios. This should be taken into consideration in future discussions on drug price revisions."

Regarding survey results on products that are showing losses due to spiking prices, another member of the panel, Teruyuki Katori, social welfare professor at Sophia University, commented that there are a total of 13,370 products on the NHI price list to start, and that 696 only accounts for a very small portion.

"Discussions will be necessary at a later phase on whether this number should be considered as large or small, as that will lead to the question of how much impact it has on the market as a whole," he said.

Building Patient Trust and Improving Transparency Through AI

(Source: An article by Andrea Park for FiercePharma)

As artificial intelligence technology becomes increasingly embedded in the pharma industry, it also increasingly is seen as a concept that can often inspire fear due to lack of understanding. For this reason, it is imperative that AI developers, particularly those in medtech, work to build trust with use and be transparent not only about how their algorithms work, but also about their intended results and how patient data will be used. This was the key takeaway point during a panel session at the AdvaMedtech conference in Boston earlier this month.

Yuri Maricich, M.D., the chief medical officer and head of development at Pear Therapeutics, pointed out that a core part of creating that transparency with both doctors and patients lies in the way AI-based technologies are labeled and marketed.

"One of the key things that we can all do is try to standardize in as many areas as possible," he said, including educating patients about how these new technologies will use their health data.

"Typically, when we make a pure hardware or a pill, patients aren't expecting to give their information back to the manufacturer. With connected devices, we're asking them to give their information back to the manufacturer, so we have this almost sacred duty to protect that data if we are going to maintain trust," Maricich said. "If we violate that trust, it is going to make it so much harder for all of us to actually bring technologies that are really effective."

Cassie Scherer, Medtronic's senior director of digital health policy and regulatory strategy, suggested that more flexible labeling policies from the FDA could help AI developers do a better job of reaching users where they are.

"Some patients read the label…but there's a lot who just want to know, 'What do I do with this? How do I use it and feel better?" she said. "And it's the same thing for physicians, where the amount of information that's given depends on the technology, and how they're using it in the clinic."

One possible solution is electronic labeling, Scherer said, which do a better job than physical labels in keeping up with any updates or modifications to an AI algorithm over time. Electronic labels can also be adapted to a wider range of patient needs, with different languages, various text options to help those who are visually impaired and the potential to even add video content to a label.

The FDA is on board. "Especially with software, we have an opportunity to think beyond the label," Brendan O'Leary, acting director of the FDA's digital health center of excellence, said during the panel. "Patients don't read labeling for the most part – and why should they? But they do use these products. So how do you have a positive experience that answers the basic patient question: 'How do I know this will work for me?'"

With that key question in mind, he said, digital technologies represent "a real opportunity to move past some of the traditional frameworks and into models that can work better for patients."

In Brief (cont.)...

nationwide when compared to the 2021-2022 flu season, and has more than doubled over the past two weeks.

- The U.S. Food and Drug Administration approved **AstraZeneca's** cancer immunotherapy drug *tremelimumab,* its first FDA approval. It will be sold under the brand name *Amjudo* and will be used in combination with the company's PD-L1 inhibitor *Imfinzi* for treating unresectable hepatocellular carcinoma, the most common type of liver cancer.
- **Pfizer** revealed on an investor call that it is considering a private market price for its COVID shot, *Comirnaty*, between US$110 and US$130 per dose. The vaccine, co-developed with BioNTech, has been available for free by the U.S. government, but stockpiles will likely run out in the first quarter of 2023, which will coincide with the new price offering.
- **Viatris Pharmaceuticals Japan** announced a plan to discontinue 33 products (mainly generics) marketed by the **Viatris Group**. They will be delisted after their transition period, which is expected to be set through the end of March 2024. Of the 33 products, 32 are distributed by Viatris and one by Mylan EPD under the group. Viatris cited "various reasons" for the discontinuation of the products, including difficulties in resuming production.
- **GSK** is streamlining its drug and vaccines businesses after spinning off its consumer health division (now **Haleon**.) The company announced it is "bringing together our medicines and vaccines manufacturing networks, and equivalent commercial operations," according to a company spokesperson, in an effort simplify its operations.
- The **U.S. Food and Drug Administration** has issued an emergency use authorization for the *Novavax* COVID-19 vaccine, and the **U.S. Centers for Disease Control and Prevention** has recommended its use to provide a first booster dose at least six months after completion of primary vaccination with an authorized or approved COVID-19 vaccine to individuals 18 years of age and older for whom an FDA-authorized mRNA bivalent COVID-19 vaccine is not accessible or clinically appropriate, and to individuals 18 years of age and older who elect to receive the Novavax COVID-19 vaccine, adjuvanted because they would otherwise not receive a booster dose of a COVID-19 vaccine.

(Sources: Company Press Releases, Drug Store News, FiercePharma, Pharma Japan, PharmaVoice, and World Pharma News)