



Steps Are Being Taken by U.S. Agencies to Address Drug Shortages

(Source: An article by Sandra Levy for Drug Store News)

The Association for Accessible Medicines (AAM) commended the U.S. Federal Trade Commission (FTC) and the Department of Health and Human Services (HHS) in their ongoing efforts to understand generic drug shortages and the possible impact on shortages caused by group purchasing organizations and drug wholesalers.

The FTC and HHS issued a formal Request for Information (RFI) "to help uncover the root causes and potential solutions to drug shortages."

"AAM commends HHS and FTC for seeking input on the impact of group purchasing organizations and wholesale distributors on the sustainability of generic drug competition," said David Gaugh, interim President and CEO of AAM. "This year represents the 40th anniversary since the enactment of the landmark *Drug Price Competition and Patent Restoration Act of 1984* (also known as the "*Hatch-Waxman Act*"). But the generic industry and the savings made possible through Hatch-Waxman, more than US\$408 million last year alone, face unprecedented threats."

AAM has released a white paper highlighting the sustainability challenges facing the industry, working with IQVIA to establish the facts around drug shortages and has articulated the causes and solutions to drug shortages. "We look forward to working with HHS and FTC in this effort," AAM said.

Gaugh continued, "Generic prices are decreasing, drug purchasers are becoming more concentrated, new generics are not adopted as quickly, some generics are never launched due to limited commercial opportunities and registered manufacturing sites are declining. As a result of all of this, the risk of drug shortages will only increase without action to bolster the long-term sustainability of generic manufacturing. Group purchasing organizations (GPOs) and wholesalers are most definitely a part of the solution to drug shortages."

The FTC and HHS are seeking public comment through an official RFI regarding market concentration among large healthcare GPOs and drug wholesalers as well as information detailing their contracting practices. The joint RFI seeks to understand how both GPOs and drug wholesalers impact the overall generic pharmaceutical market, including how both entities may influence the pricing and availability of pharmaceutical drugs.

The U.S. Healthcare Distribution Alliance (HDA) commented on the issue, "The request for information issued by the Federal Trade Commission and Health and Human Services is the latest in the ongoing dialogue between policymakers, regulators and healthcare supply chain leaders about the root causes of the drug shortages--and solutions required to avoid future supply disruptions and their far-ranging impact on patients. HDA
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- ♦ The **U.S. Department of Justice (DoJ)** has launched an antitrust investigation into **UnitedHealth**, owner of the biggest U.S. health insurer and a leading manager of drug benefits with a large network of doctor groups. Investigators are questioning industry officials who compete with UnitedHealth, asking about issues including certain relationships between the company's insurance unit, **UnitedHealthcare**, and its **Optum** health-services unit, which own physicians' groups and other assets. UnitedHealth executives have stated that Optum and UnitedHealthcare do not favor one another, and routinely work with competitors.

- ♦ Pharmaceutical manufacturer **AbbVie** announced that President and COO *Robert Michael* will take over as CEO effective July 1, 2024. AbbVie's current CEO, *Richard Gonzalez* will move into the role of Executive Chairman. Michael is a 31-year veteran of AbbVie.

- ♦ German manufacturer **Boehringer Ingelheim** hopes to launch drug candidate *survodutide* (co-developed to treat

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Drug Supply in Japan Worsens Amid Flu Surge and Shipment Halts

(Source: An article by Takashi Ebisawa for Pharma Japan)

Drug supply situations have worsened for three consecutive months from October through December of 2023, according to the Federation of Pharmaceutical Manufacturers' Associations of Japan (FPMAJ). Industry experts blame the shortages on an influenza outbreak as well as increasing shipment suspensions.

As much as 25.9% of all ethical medicines had their shipments either restricted or suspended as of December, the highest since April of 2023 when the FPMAJ changed its drug supply survey to a monthly format. As culprits, industry officials cite surging demand for antitussives and expectorants amid the influenza wave and suspended shipments due to manufacturing and quality issues.

The generic industry has been rattled by a spate of manufacturing deficiencies, starting with GMP violations found

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Drug Shortages (cont.)...

will respond to the RFI detailing our industry operates and the important role it plays in managing and mitigating drug shortages.”

“When shortages do occur, distributors actively work to mitigate the impact on patients and healthcare providers. Our industry regularly monitors for spikes in demand or dips in availability for products and proactively communicates with manufacturers, industry provider partners and regulators. To prevent seasonal-related drug shortages, distributors work with manufacturers well in advance to help forecast demand for medicines and take the risks that accompany each season. When demand or supply shortages necessitate, our members identify and substitute safe and effective products as well as individually deploy allocation programs to create safeguards for products in high demand and help prevent overstocking by customers due to their fear of market shortages. The bottom line is that our industry is successful only when products are moving, pharmacy shelves are full and, critically, patients have the medicines they need.”

Drug Supply in Japan (cont.)...

at Kobayashi plant in January of 2021. This was followed by administrative penalties that also hit Nichi-Iko Pharmaceutical, Choseido Pharmaceutical, and Kyowa Pharmaceutical Industry, among others, over their respective issues. As these companies continue to improve their operations, they have restricted or suspended shipments of many products, which prompted orders to other manufacturers, forcing them to restrict their own supplies.

Major generic drug makers are working to ramp up production to improve the situation. In FY2023, Towa Pharmaceutical and Sawai Pharmaceutical alone have increased production by a combined total of 5 billion tablets, respectively increasing output to 14.2 billion tablets and 14.2 billion compared to FY2021.

Despite these efforts, the FPMAJ’s latest survey shows that drug shortages are worsening. The survey, which collects information from FPMAJ member companies on supplies of all ethical drugs on the NHI price list, has been conducted each month since April of 2023.

The percentage of goods with restricted or suspended shipments remained steady at around 22% from April through September of 2023, but the situation has deteriorated since then. The figure rose to 23.7% in October, 24.4% in November and 25.9% in December.

An official from one generic manufacturer attributed the worsening supply situation to the spread of influenza, which has seen a rise in cases since August 2023 (and peaking in early December.) Since there were no significant influenza outbreaks during the COVID-19 pandemic, companies reduced their production of necessary medications, and in FY2023, they based production on the previous year. However, influenza resurged in FY2023, making it difficult to keep up with the demand for influenza medicines.

Another industry official noted that the negative supply trend might have also been driven by the increasing number of products hit by suspended shipments resulting from manufacturing and quality issues. Companies are dealing with a variety of challenges including suspended production due to GMP issues, inability to easily eliminate discrepancies between

granulation instructions and actual manufacturing processes, and defects in purity testing.

There is hope that situation will improve once generic makers that have deferred plans to manufacture other solid formulations due to requests by the MHLW will be able to shift production back to other products in short supply after flue cases recede.

One item of note, a new health coverage scheme will be introduced for long-listed products (LLPs) in October. Since the new scheme will involve additional copayments and is quite complex, some medical institutions and pharmacies are expected to switch from LLPs to generics in April, upon the NHI price revision, rather than wait for the new system to take effect. If this boosts the demand for generics, the supply situation could worsen.

In Brief (cont.)

obesity and fatty liver with **Zealand Pharma**) in 2027 or 2028, contingent on favorable trial data. Sources at Boehringer said that it was not yet clear in which one of the two targeted indications the drug would be launched.

- ◆ **Moderna** said in its most recent earnings call that the company is moving away from its coronavirus vaccine (**Spikevax**) and onto other mRNA products in development. Moderna reported positive numbers on the performance of *Spikevax*, with reported sales of US\$6.7 billion. This was a decline in sales compared with 2022, but Moderna’s fall was not as sharp as Pfizer’s *Comirnaty* sales. *Spikevax* revenue for the quarter came in at US\$2.8 billion, beating analysts’ expectations.

- ◆ **GSK** announced the completion of its acquisition of **Aiolos Bio**, a clinical stage biopharmaceutical company focused on respiratory and inflammatory conditions. GSK will pay US\$1 billion upfront and up to US\$400 million in success-based milestone payments.

- ◆ Companies are now testing drugs like **Novo Nordisk’s semaglutide (Ozempic and Wegovy)** and **Eli Lilly’s tirzepatide (Mounjaro and Zepbound)** to treat metabolic dysfunction-associated steatohepatitis (MASH), formerly known as non-alcoholic-related steatohepatitis (NASH). The condition affects approximately 115 million adults globally, driving a market that could reach US\$27 billion by 2029.

- ◆ The Japanese ethical drug market crossed ¥11 trillion (US\$72.9 billion) in 2023 for the first time since data started being recorded in 2005 on the back of strong performances in the oncology space, according to **IQVIA Japan**. The statistics are based on data from wholesalers and do not reflect medicines distributed through other channels. Subsequently, data for COVID-19 vaccines and certain other drugs are not included.

- ◆ The U.K.’s **NHS** has launched a new campaign to raise awareness of the seven additional conditions that patients can treatment from pharmacies without needing to see a general practitioner. *PharmacyFirst* enables patients to consult their local pharmacy for sinusitis, sore throat, earache, infected insect bite, impetigo, shingles, and uncomplicated urinary tract infections. The new campaign will run through advertisements on demand TV services, bus stops, billboards, and social media to encourage people to use their local pharmacy for a wider range of illnesses.

(Sources: Drug Store News, FiercePharma, Pharma Japan, PharmaVoice, Reuters & World Pharma News)