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Europe Names Critical Medicines in Effort to Counter Drug Shortages

(Source: An article by Fraiser Kansteiner for FiercePharma)

Over the past several years, drug shortages have exasperated doctors and patients on both sides of the Atlantic, prompting lawmakers and government agencies to take action in both Europe and the U.S. Now, following the debut of a short-term plan to combat these supply shortages across the European Union this winter, European officials are taking a holistic look at the medicines most likely to be scarce.

The European Medicines Agency (EMA) presented a list of more than 300 critical generic drugs that could be subject to future shortages. Inclusion in the list doesn't mean a particular drug is likely to experience a shortage anytime soon, the EMA explained in a press release. However, the list spotlights therapies for which the prevention of shortages is "particularly important" given the risk of "serious harm to patients" if supply is interrupted.

The medicines on EMA's list include basic antibiotics such as amoxicillin, plus painkillers like paracetamol and morphine, as well as vaccines for diseases such as measles, rabies and the flu.

European officials narrowed down the final roster from an initial review of some 600 solo and combination therapies. EMA says it plans to update and extend the catalog next year.

Europe will use the critical drugs master list to define medicines requiring "additional measures" to strengthen supply and prevent future shortages. Furthermore, the European medicines regulatory network will monitor the drugs on the list and implement certain measures to minimize supply disruptions, the EMA added.

Specific supply security measures could take the form of recommendations for companies to diversify suppliers or boost production in the European Union, alongside investment incentives, additional regulatory obligations and procurement contracts, the EMA explained.

For months now, Europe has been on a quest to lessen the impact of drug shortages in the bloc.

Back in October, the European Commission rolled out a short-term plan to help combat drug shortages, including plans to draft the critical medicines list. At the time, the Commission said the list would help guide decisions and mitigate the continent's overdependence on generic medicines and drug ingredients from India and China, respectively.

Another short-term measure included in the Commission's plan took the form of the Voluntary Solidarity Mechanism for medicines, under which countries will share their stocks of drugs as others in the bloc face shortages.

The European Commission is also setting up a Critical Medicines Alliance—due to come online in early this year—that will enable national authorities to cooperate with industry and the EU to counter shortages and supply chain vulnerabilities. The goal of the alliance is to pave the way for potential legislation.

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- Pharmacy organizations, including the **National Association of Chain Drug Stores (NACDS)** and **National Community Pharmacists Association**, applauded the recent passage of the *Lower Costs, More Transparency Act (H.R. 5378)* by the U.S. House of Representatives. The bill is a vital aspect of pharmacy benefit manager reform. Among its provisions, it addresses the "pharmacy benefit manipulation" that harms the most vulnerable in Medicaid, NACDS noted.
- **Merck & Co.** and **Moderna** unveiled new three-year data in melanoma patients for their novel individualized neoantigen therapy combination with *Keytruda* which showed improved recurrence free survival and cutting the risk of recurrence of death by 49%. It also was shown to cut the risk of distant metastasis or death by 62% compared with *Keytruda* alone following complete resection in stage III/IV melanoma patients with high risk of recurrence.
- **Johnson & Johnson** is conducting a "comprehensive review" of its portfolio and plans to operate its vaccines and infectious diseases outfits as one group, according to the company. The company will continue to invest in all therapeutic areas while "deprioritizing some programs" while its infectious disease pipeline will undergo a major overhaul. The company is also winding down its COVID-19 and HIV

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Japan's Health Ministry Panel Explores Vision for Generic Industry

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

The Ministry of Health, Labor, and Welfare (MHLW) is in the final stage of compiling a report that calls for a structural transformation of the Japanese generic industry.

The MHLW solicited opinions on the ideal state of the sector at a session by its panel dedicated to the study of the generic industry. Some members proposed the creation of "consortia" for the industry shake-up, while others lobbied for structural reform over a span of approximately five years or a common "vision" to be presented by the government.

According to the MHLW, which held a media briefing after a closed-door meeting, the day's agenda was two-fold and included the reporting of the FY2024 drug pricing reform package and discussions to clarify the "ideal state" of the generic industry. No comments were made by the panel members concerning the pricing reform, according to ministry officials.

The MHLW plans to issue a report of the panel's opinions at a later date, of which the main theme will be the "ideal state" of the generic industry. The handouts by the MHLW explained the current landscape of the sector, pointing out the rise in manufacturing costs and labor shortages that could also

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fuel this trend. The ministry also raised the need for reinforced compliance in the industry, noting the number of flaws detected in manufacturing and quality control.

In light of such managerial issues, the MHLW presented the discussion, "What is the ideal state of companies and the industrial structure that would enable the stable supply of generics with ensured quality?" As examples of perspectives to be considered, the MHLW raised 1) business models, 2) product portfolios, 3) manufacturing methods, 4) organization and other business structures, and 5) the ideal number of products (per API). The ministry also sought opinions on ways to change the industrial structure and the optimal timeline.

According to the MHLW, during the Q&A session, certain members agreed with the proposal previously suggested by panel member Atsushi Yasumoto, president of GMP regulatory consultation firm Nexredge, to reshuffle the industry by forming consortia. There were also comments such as, "Since it is difficult to suddenly cooperate in manufacturing, why not start with quality control, an area particularly short-handed?" and "Integrating systems can be another possible path to follow."

The ministry said that some members see "around five years" as an appropriate time frame to implement structural transformation, considering the time required to establish a quality control system, the managerial resilience of companies, and the alleviation of supply disruption issues that continue to this day. Other voices included, "The deadline should be set for incentives targeting generic makers" and "A culture of executing reform must be fostered," according to the MHLW.

Meanwhile, one member was quoted by the ministry as saying, "A significant amount of money will be necessary to rebuild the aging plants of generic makers. Government subsidies are not enough to address this, and support from financial institutions is necessary. To boost the attractiveness of the industry and make financial institutions feel reassured, the government must set out its vision and the direction that the industry is to pursue."

An MHLW official told the press after the meeting, "Although the panel's final output will take the form of a report, it is expected to include the ideal state of generics and examples of measures toward achieving such a state and might thus be approximate to an industry vision." Details will be decided going forward, taking into account the opinions of the panel members. The next panel meeting is scheduled for January 31, 2024.

Pharma Manufacturers Kick Off 2024 with Price Hikes

(Source: An article by Fraiser Kansteiner for FiercePharma)

While public and political scrutiny around U.S. drug pricing has reached a fever pitch in the wake of 2022's Inflation Reduction Act (IRA), that hasn't stopped pharma majors from ringing in 2024 with a round of medication price hikes.

Companies such as Pfizer, Sanofi and Takeda are raising prices on more than 500 drug doses and formulations this month. Taking different doses and formulations out of the mix, more than 140 medicine brands will see their prices increase in January, according to Reuters.

Once again, Pfizer stood out among its peers for January price hikes, with its increases accounting for more than a quarter of all medicines included in this round. Specifically, Pfizer is bumping up the prices on 124 doses or formulations, plus another 22 from its sterile injectables arm Hospira.

Taking the various doses and formulations out of the equation, Pfizer and Hospira will raise the prices of 30 generic and six branded drugs, respectively, according to the report.

Coming in second is Takeda's Baxalta, which is planning the second-highest number of price increases at 53, followed by UCB Pharma, which is increasing costs on 40 products.

Last year, drugmakers raised the prices of 1,425 drugs, slightly less than in 2022, when 1,460 drugs received price hikes.

Meanwhile, not all medicines are getting higher prices this year. GSK, for instance, plans to cut costs on some asthma, herpes and anti-epileptic drugs in 2024, the company announced. GSK and two other companies are expected to lower prices on at least 15 medications in January.

January's price hikes isn't likely to surprise industry watchers, who know that drugmakers routinely use the first day of the year, and sometimes July 1, to raise their list prices. Meanwhile, more price hikes are likely to be announced over the course of January, which is typically the most popular month for the move.

The first round of price increases comes as Washington, D.C., officials and lawmakers work clamp down on high drug costs in the United States. Aside from giving Medicare the power to negotiate certain drug costs starting in 2026, the IRA aims to limit price hikes to the rate of inflation—a policy set to take effect early this year.

Back in mid-December, the White House flagged 48 Medicare Part B drugs that saw their prices grow faster than the rate of inflation in the final quarter of 2023. Starting in January, some Medicare patients who receive the 48 selected drugs—which include medications to treat cancer and fight infections—could have lower coinsurance than what they would have paid otherwise, the White House added last month.

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vaccines. Moving forward, the company plans to focus on pre-exposure prophylaxis to flu, COVID-19, RSV and HRV.

- **Pfizer** has completed its US$43 billion acquisition of **Seagen**, doubling its pipeline to 60 programs, according to Pfizer. With the addition of four FDA-approved cancer drugs – *Adcedris, Padcev, Divdak* and *Tukysa* – Pfizer now has nine oncology medications that are already blockbusters or have blockbuster potential. "Given Seagen's position as the best ADC company, we are confident they are the ideal partner for Pfizer," *Albert Bourla*, Pfizer CEO, said during a conference call. "Pfizer is ideally situated to deploy our financial, scientific, manufacturing and commercial capabilities to develop far more new medicines with Seagen's targeted technology.
- **Genentech's** interim chief executive, *Ashley Magargee*, has assumed the position permanently effective January 1, 2024. She replaced *Alexander Hardy*, who exited the company in November and now serves at CEO of **BioMarin**.

(Sources: Company Press Releases, FiercePharma, and World Pharma News)