IFPW FOCUS
A Bi-Weekly Pharmaceutical Industry Newsletter
Vol 34 | No. 15
July 31, 2025

U.S. FDA Initiates National Priority Fast Track with 2-Month Reviews of Onshoring and Affordability Projects

(Source: An article by Nick Taylor for FiercePharma)

The U.S. Food and Drug Administration (FDA) has begun accepting applications for a priority pathway designed to shorten drug candidate review times to one to two months, giving developers of medicines that align with U.S. national health priorities a fast track to market.

FDA commissioner Marty Makary, M.D., recently unveiled the program, and the FDA opened the Commissioner's National Priority Voucher (CNPV) Pilot Program for applications and revealed details of the program on July 22nd. This includes the dissemination of more information on the types of products that may be eligible for the initiative and how the agency plans to accelerate regulatory reviews.

The FDA listed five priorities that products accepted into the plan could address – up from four when the program was first announced – and provided examples of the types of medicines that could meet the CNPV eligibility criteria.

"Increasing affordability" is the newly added fifth priority. The FDA said a company could access the pilot program via the affordability route if it "lowers the U.S. price of a drug or drugs consistent with the Most Favored Nation pricing or reduces other downstream medical utilization to lower overall healthcare costs."

The FDA also revised the wording of a priority that covers domestic manufacturing. Under the updated priorities, the FDA is focused on "onshoring drug development and manufacturing to advance the health interests of Americans and strengthen U.S. supply chain resiliency."

FDA officials cited "a clinical trial that maintains robust U.S. enrollment to support generality for Americans against the U.S. standard of care" as an example of a project that could meet the onshoring criteria. The FDA recently rejected a Roche request for approval over a lack of evidence on the effects of the drug in U.S. patients, and the FDA has called for a higher proportion of local patients in the studies.

The other three priorities are unchanged from the June notice, but the FDA has provided new examples. The agency cited "a universal flu vaccine that could provide broad protection against multiple strains of influenza, including those with pandemic potential," as an example of a product that could address a U.S. public health crisis.

Drugs that treat or prevent rare diseases or address "America's chronic disease crisis" could meet one of the other priorities. The FDA also further explained the priority to deliver more innovative cures, explaining that the aim "is transformative impact that far outstrips the threshold for breakthrough therapy designations. Examples include drugs that re-program the

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In Brief...

- **Johnson & Johnson** reported Q2 2025 sales growth of 5.8% to US$23.7 billion with operational growth of 4.6% and adjusted operation growth of 3.0% despite major challenges from the loss of exclusivity of its immunology blockbuster Stelara. Strong operational performance and favorable foreign exchange resulted in the company increasing full year estimated guidance. "Today's strong results reflect the depth and strength of Johnson & Johnson's uniquely diversified business operating across both MedTech and Innovative Medicine," said Chairman & CEO *Joaquin Duato*.
- A federal district court in Delaware sided with **Mylan**, now part of **Viatris**, in a patent litigation case over a proposed generic to the GLP-1 obesity blockbuster, *Wegovy*. The court disputed **Novo Nordisk's** argument that Mylan's FDA application for its generic encourages doctors and patients to infringe on a patient held by Novo. The case focuses on a single patent, known as #003 patent, which covers treatment methods using the drug.
- **Merck** announced a cost-cutting plan designed to save the company US$3 billion by the end of 2027. The company, which has faced declining sales of HPV vaccine *Gardasil* and the impending loss of patent protection for its cancer blockbuster, *Keytruda*, said the savings will be "fully reinvested" to support "new product launches". Earlier this year, the company touted 20 products in its pipeline that have blockbuster potential, and could provide US$50 billion in annual revenue.
- **Oriola Corporation** (Finland) announced Q2 financial results with net sales growing by 12% to €494 million (US$570.6 million). The strong growth is attributed to its distribution and wholesale segments. "In the second quarter,

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Key Considerations When Preparing the Supply Chain for Climate Change

(Source: A staff article by European Pharmaceutical Manufacturer)

Global distribution of life-saving pharmaceuticals is incredibly complex, with several different components from warehouse to final delivery. At each stage, providers must make sure strict temperature requirements are met across varying climates and infrastructures. Here are some key considerations when preparing the cold chain for climate change.

Cold chains need to be smarter and stronger. One key consideration is that as weather becomes increasingly volatile, cold chains need to become smarter and stronger. Supply chain disruptions can easily cause issues with the delivery of supplies and treatments. Global warming is creating unpredictable conditions, with flooding, landslides and storm damage. These extreme weather fluctuations will impact routes and mean that

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Key Considerations *(cont'd.)*...

future packaging may need to handle freezing temperatures, extreme heat and humidity all in one journey.

Ensuring reliability and efficiency is vital. Availability of packaging solutions must be successfully managed, and the industry must position itself to be able to predict and prepare for all disruptions. Extreme weather fluctuations will mean a one-size-fits-all approach will no longer be viable. Instead, data-driven risk analysis and route-specific adaptation will be key. Manufacturers will need to factor in seasonal and regional climate risks when planning distribution.

One solution to these evolving challenges is integrating AI into the cold chain. AI-driven insights can help optimize routes, reduce waste and lower costs. By analyzing historical data and predicting climate patterns, the most efficient, reliable and unaffected delivery routes can be determined. This not only cuts costs but also supports the timely and reliable delivery of medicine and minimizes environmental impact. AI will need real-time data on transportation conditions, such as weather patterns and temperature fluctuations, to determine the correct route and solution type needed for a successful delivery.

The widening of the global health gap. Affluent countries, with infrastructure already in place, are in a relatively strong position to manage the rising prices of climate-proof logistics. However, underserved regions without this infrastructure will face a double burden - the impact of severe climate change combined with the weakest infrastructure. Extreme heat and flooding, on top of the ruralness of some locations, will introduce increased complexity into logistics. As reliable distribution grows increasingly expensive, lower-income regions run the risk of being behind when it comes to global pharmaceutical distribution.

Demand for pharmaceuticals in these regions will also rise. Floods, landslides, wildfires and drought can quickly cause a humanitarian crisis, especially in areas that are unprepared to handle these events. Resource constraints will leave these regions struggling to both adapt to climate change and meet the rising costs of pharmaceuticals. As global warming worsens, global collaboration will be vital to support these nations.

Handling global warming requires true collaboration. Finally, as learned from any previous crisis, collaboration is key. The current reality is that oftentimes, someone vital left out of the conversation.

As witnessed during the pandemic, packaging providers played a crucial role in the delivery of lifesaving medicines. By building relationships with these providers now, logistics can adapt to ensure continued effectiveness of cold chain distribution as we prepare for the increase of extreme weather.

Only by fostering collaboration between manufacturers, logistics partners and packaging providers can the pharmaceutical industry hope to balance sustainability, cost and reliability in the face of global warming. New technology and AI will be key drivers of this, along with the agility to react fast to any potential disruption.

Companies that prepare now and find the right balance will be more efficient and gain a competitive edge in a market that demands both resilience and responsibility.

U.S. FDA *(cont'd.)*...

immune system to fight multiple diseases.

The FDA is asking companies that think they meet the criteria to submit a description of 350 words or less of how the program aligns with one of the national health priorities. Companies should provide information about the disease, the potential impact of the drug, the current stage of development and any unique aspects of the approach that make it particularly relevant to the chosen priority.

The FDA will select five companies to participate in the pilot program in the first year. To accelerate reviews, the FDA will convene a senior multi-disciplinary review committee as part of the Office of the Chief Medical and Scientific Officer.

In Brief (cont.)

net sales grew, and sales margin improved, and the underlying distribution business remained strong. In the operating environment, we continue to see overall uncertainty which is reflected in continued weak consumer confidence. On the other hand, the overall pharmaceutical distribution market saw good growth," said *Katarina Gabrielson*, Oriola's CEO.

- **Novo Nordisk** has named *Maziar Mike Doustdar* as its new CEO. Doustdar will succeed *Lars Fruergaard Jørgenson* and will assume his new position on August 7th of this year. The CEO transition comes as Novo struggles to maintain its lead in the weight-loss market amid growing competition from Eli Lilly and GLP-1 compounders.
- Pharmaceutical manufacturer **Roche** is considering pursuing a direct-to-consumer model to eliminate the need for pharma "middlemen". Pharmacy benefit managers and drugmakers have blamed each other for high U.S. drug prices with manufacturers calling out PBMs for prioritizing drugs with higher costs in order to collect higher rebates. Roche's CEO suggest that the U.S. cut drug prices in half, "take out these people in the middle" who don't contribute "at all" to innovation but reap the benefits without assuming any risk.
- With the threat of tariffs imported to the United States, **AstraZeneca** unveiled a plan to invest US$50 billion in the U.S. by 2030. The spending plan includes plans for a multi-billion dollar facility in Virginia and is in addition to a US$3.5 billion capital investment by the company revealed in November of 2024 after the election of President *Donald Trump*. "It is really a vision that the administration is sharing for the U.S. economy, U.S. development to create highly skilled jobs and expand manufacturing in the U.S.," company CEO *Pascal Soriot* said during a press conference in Washington, D.C.
- **Purdue** President *Mung Chiang* and **Eli Lilly** Chairman and CEO *David Ricks* announced an expansion of their long-standing academic agreement with Lilly's planned investment of up to US$250 million for their collaboration over the next eight years. The partnership, which has the potential to be the largest ever industry-academic agreement of its kind in the U.S., will seek to accelerate innovation at every stage of the pharmaceutical pipeline.

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