

ANSWERS TO QUESTIONS YOU AND YOUR COLLEAGUES MAY HAVE



Physicians, nurses, pharmacists, and other healthcare professionals are understandably concerned about the ongoing supply shortages. Starting below you'll find answers to questions you may encounter when speaking with other healthcare professionals within your institution about the Pfizer Injectables supply recovery efforts. If you have additional questions, do not hesitate to reach out to your Pfizer Representative.

WHEN WILL THE SUPPLY SHORTAGE BE RESOLVED?

We continue to make progress in our recovery plan, and while many products will have ongoing deliveries throughout 2018, full recovery of all products is currently projected by the middle of next year. You can visit our supply recovery-specific website at PfizerInjectablesSupply.com to view the most up-to-date information on product availability. Contact your Pfizer Representative to sign up for a personalized supply availability report specific to your institutions. You can also reach our Supply Continuity Team between 7:00 AM and 6:00 PM CT to discuss any product availability questions you may have. They can be reached at 1-844-646-4398 (select Option 1 if you are a Pfizer customer, then Option 3 [Supply Continuity Team]) or at PISupplyContinuity@Pfizer.com.

WHAT IS THE STATUS OF SUPPLY GOING FORWARD?

Pfizer Injectables remains committed to a sustainable supply of sterile injectable products. We are fully dedicated to restoring supply.

While the causes of individual shortages vary, the majority are due to 3 main factors—manufacturing, distribution, and third-party supplier delays. Our recovery plan includes efforts aligned to each of these factors, with select products continuing to recover through the summer. Our recovery plan includes work streams aligned to each of these factors, with select products continuing to recover through Q2 2019, and many other products fully recovering by mid-year 2019.

Beyond our commitment to resolving the current supply shortage, we are also working to minimize supply shortages in the future. We will have invested \$800 million in capital in our injectables manufacturing network by the end of 2018. In addition, an incremental \$1.3 to \$1.4 billion investment will be made in these important facilities over the next 5 years.

We are also working on a plan to increase safety stock so we have additional inventory to help mitigate possible future shortages.

We are focused on organizational preparedness and communications infrastructure so that we can communicate quickly and thoroughly, especially in times of supply shortages.

DO YOU HAVE EMERGENCY STOCK FOR THE PRODUCTS THAT ARE CURRENTLY IN SHORTAGE?

Emergency orders can be considered for products on market reserve. You will need to work with your Pfizer Representative and the Supply Continuity Team. They can be reached at 1-844-646-4398

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? **HOW ARE MEDICATIONS PRIORITIZED?**

Pfizer Injectables is prioritizing the manufacture of medically necessary products, as determined by customer feedback and our US Medical Affairs team.

? **IS THERE A PLAN TO SAFEGUARD RECOVERED PRODUCTS FROM BEING IN SHORTAGE AGAIN?**

Part of our investment is in creating increased capacity to help handle future surges in demand. We are making significant investments to increase capacity. For example, for some critical products, we are looking at dual sources to increase safety stock, as well as working with the FDA to extend the shelf life of these critical products.

? **CAN YOU TRANSFER ALLOCATION ACROSS COMPANIES?**

The DEA CII manufacturing allocation is site-specific and not transferrable. The DEA does not permit a company to transfer all nor part of their allocation to another company. However, the DEA does retain the right to revise a company's allocation at any time during the year.

? **DO YOU SUPPORT EXPANDING THE DEA QUOTA OF CONTROLLED SUBSTANCE ALLOCATION TO OTHER SUPPLIERS?**

The DEA and FDA are fully aware of our shortage, and we continue to update them regularly. Each sterile injectable opioid product we manufacture has specific DEA allocation numbers. Since 2016, Pfizer has met our initial allocation numbers. When we have identified additional customer need, increased allocation was granted to us by the DEA.

Regarding the 2018 Pfizer allocation, Pfizer is relinquishing a portion of its hydromorphone quota in the short term. We will continue to work with the DEA as the year progresses to request or relinquish our procurement quota as required.

? **WHAT IS THE STATUS OF THE McPHERSON, KS, MANUFACTURING FACILITY?**

Following the October 2017 inspection, the FDA has upgraded the status of the McPherson site to Voluntary Action Indicated (VAI). Pfizer considers this development another step closer toward launching new products from our McPherson site, as we continue with our commitment to manufacturing and delivering quality products.

? **WHAT ARE THE MAIN FACTORS CONTRIBUTING TO THE SHORTAGE?**

While the causes of individual shortages vary, the majority are due to 3 main factors—manufacturing, distribution, and third-party supplier delays. Of our manufacturing issues, some are being remediated, which can slow down production and contribute to supply shortages. For example, we have experienced issues with our sterilizing equipment (autoclaves) during requalification/testing, which we are addressing.

Our recovery plan includes work streams aligned to each of these factors, with select products continuing to recover through the summer, while others have already recovered. Pfizer Injectables is committed to ensuring that Good Manufacturing Practice (GMP) and Pfizer standards on quality are met.

? **WHAT IS PFIZER DOING TO KEEP GRAY MARKET VENDORS FROM HOARDING PRODUCTS?**

Pfizer does not engage with gray market vendors or condone gray markets as a business practice. Every agreement Pfizer Injectables has with our trading partners includes a provision that strictly prohibits selling to anyone who plans to resell the product. If we are notified that our product is available through the gray market, we attempt to trace who sold the product to the gray market and no longer ship our product through that channel.

? **ARE THERE OTHER SUPPLIERS OF THE PRODUCT IN SHORT SUPPLY?**

Alternative suppliers for products experiencing a shortage should be considered individually for each patient, depending on the clinical condition. While Pfizer is unable to make product recommendations, it is important to note that there may be other treatment alternatives for certain medications.

? **HOW DOES PFIZER PLAN TO MINIMIZE FUTURE SHORTAGES?**

Beyond our commitment to resolving the current supply shortage, we are also working to minimize supply shortages in the future. We are investing in our business with an incremental \$1.3 to \$1.4 billion investment planned for expanding manufacturing capabilities over the next 5 years.

We are also working on a plan to increase safety stock so we have additional inventory to help mitigate a possible shortage.

We are focused on organizational preparedness and communications infrastructure so that we can communicate quickly and thoroughly, especially in times of supply shortages.

? **WHAT IS THE SUPPLY CONTINUITY TEAM?**

The Supply Continuity Team is a dedicated team that works with you and your sales representatives on a wide range of supply needs, including order placement and fulfillment information, live ordering and customer service troubleshooting, as well as assisting with up-to-date product availability information. You can reach the Supply Continuity Team between 7:00 AM and 6:00 PM CT to discuss any product availability questions you may have. They can be reached at 1-844-646-4398 (select Option 1 if you are a Pfizer customer, then Option 3 [Supply Continuity Team]) or at PISupplyContinuity@Pfizer.com.

? **HOW CAN WE FIND PRODUCT STATUS AND AVAILABILITY?**

Transparency of supply-related communication is one of our main priorities. You can visit our supply recovery-specific website at PfizerInjectablesSupply.com to view the most up-to-date information on product availability. Contact your Pfizer Representative to sign up for a personalized supply availability report specific to your institutions. You can also reach our Supply Continuity Team between 7:00 AM and 6:00 PM CT to discuss any product availability questions you may have. They can be reached at 1-844-646-4398 (select Option 1 if you are a Pfizer customer, then Option 3 [Supply Continuity Team]) or at PISupplyContinuity@Pfizer.com.



WHAT PRODUCTS HAVE BEEN ISSUED AN EXPIRATION DATE EXTENSION BY THE FDA?

Please visit the FDA website for the most up-to-date information with the full list of products and lot numbers: www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm563360.htm.

WHAT HAVE YOU ACHIEVED IN YOUR RECOVERY PLAN SO FAR?

The majority of the shortages are a result of activity at the McPherson site, which was acquired from Hospira. Since these shortages began, we will have invested \$800 million in capital in our injectables manufacturing network by the end of 2018. In addition, an incremental \$1.3 to \$1.4 billion investment will be made in these important facilities over the next 5 years. We have deployed teams from across the Pfizer Global Supply network to consult and assist with the upgrades and long-term planning efforts.

Based on an inspection of our McPherson manufacturing facility in October 2017, the FDA has upgraded the status to VAI. This is good news, and we look forward to continuing to manufacture and deliver quality products from our McPherson site. We will continue to coordinate with the FDA to explore extended dating in addition to accelerated review for validation of line transfers for key molecules.

We are also increasing inventory levels for key manufacturing materials, which include:

- Increasing safety stock targets above historical norms on medically necessary SKUs
- Growing inventory of components of critical material supporting medically necessary products
- Installing new autoclaves to support our manufacturing capabilities
- Expanding our direct shipment option to more than 250 SKUs

We understand that supply recovery is of the utmost importance to you and continue to prioritize resolving our manufacturing/technical challenges to restore supply. We look forward to communicating more on the recovery in the future.