



Product Supply and Manufacturing Strategy

EXECUTIVE SUMMARY:

Civica Rx's mission is to ensure that essential generic drugs are available and affordable to everyone. Drug shortages are creating a national crisis that is negatively impacting patient health and safety. Drug shortages are also creating inefficiencies within hospitals and unpredictable price increases that lead to budgetary instability in hospitals. In the immediate term, Civica will focus on the most critical drugs required to treat patients safely, effectively and efficiently.

Opportunists have engaged in predatory pricing. Predatory pricing has typically occurred with old generic drugs that should be in the public domain and where artificial monopolies have been established by generic drug companies. These pricing practices have in certain cases led to price increases of 1,000, 10,000 and even 100,000 percent.

Civica will promote competition and does not want to be the sole manufacturer of any generic drug. Civica is pro-competitive as we realize that a shortage of viable and willing manufacturers within the supply chain is a significant reason for drug shortages.

Civica is committed to establishing redundant sourcing and building adequate safety stock to ensure product availability. The commitment to redundant sourcing, building six months of safety stock inventory, coupled with establishing long-term contracts, will allow Civica to work with Active Pharmaceutical Ingredient (API) suppliers and generic drug manufacturers to expand existing capacity or bring up new capacity that does not currently exist in the market. This long-term commitment from Civica to purchase product at set prices alleviates uncertainty of product demand for API suppliers and drug manufacturers.

Our supply and manufacturing strategy includes three distinct approaches that are designed to create redundancy, promote competition and solve drug shortages prioritized by our health systems as fast as possible to best serve patients.

Upon studying the drug shortage issue, Civica has learned that for many generic injectable drugs undergoing a shortage, there typically are often one or two viable generic drug manufacturers who capture most of the market; however, there are multiple other generic drug manufacturers who have the US FDA approved Abbreviated New Drug Application, capable manufacturing facilities and capacity to produce the drug undergoing shortages, yet are dormant due to business and/or other reasons.

When the market is served by one or two manufacturers, any disruption in the complex, long and fragile supply chain almost immediately leads to a drug shortage, which is difficult to recover from because no other manufacturer can readily produce the required inventory.

PRODUCT SUPPLY AND MANUFACTURING STRATEGY:

Civica is deploying a three-legged stool approach to our manufacturing strategy, all of which are being simultaneously developed and deployed.

Civica Manufacturing Leg 1: Work with several manufacturers, including the dormant manufacturers who have the US FDA approval, capable manufacturing facilities and capacity to produce Civica labeled generic drugs, allowing manufacturers to re-enter the market. Civica will build safety stock to create a buffer in the event of a future disruption within the supply chain and work with these manufactures to invest in their suppliers, facilities, capacities, processes and people. These Civica labeled products will be manufactured at the direction and oversight of Civica.

Civica Manufacturing Leg 2: Develop and/or purchase Abbreviated New Drug Applications for generic drugs and work with contract manufacturing organizations to produce Civica products. Owning an Abbreviated New Drug Application increases Civica's ability to assure availability and affordability for our members.

Civica Manufacturing Leg 3: Buy and/or build Civica manufacturing facilities using Civica's Abbreviated New Drug Applications. This approach continues to increase manufacturing capacity, increase control, add redundancy, increases competition and allows Civica to provide the lowest cost product at a sustainable price.

EXPECTED RESULTS:

Through this supply and manufacturing approach, which allows Civica to have a versatile manufacturing network and opportunities for redundant manufacturing, Civica will supply critical generic medications to our member hospitals at fair prices that are sustainable for the supply chain. Civica expects to reduce generic drug shortages by:

1. Providing critical drugs to treat patients safely, effectively and efficiently.
2. Increasing competition for older generic drugs, ensuring a robust supply chain and improving availability and affordability.
3. Providing members financial stability on fluctuating drug prices associated with drug shortages.
4. Protecting members from predatory pricing.
5. Providing long-term certainty to manufacturers, so that they can invest in the manufacturing plants preventing future drug shortages.