

CIVICA®

20R 10 pcs

Civica Rx Manufacturing Approach

R20-10

Carrier 1

Highlights: Civica Rx Manufacturing

Civica Rx (Civica, Inc.) was founded in 2018 by seven health systems (CommonSpirit Health, HCA Healthcare, Intermountain Healthcare, Mayo Clinic, Providence St. Joseph Health, SSM Health and Trinity Health) and three philanthropies (the Laura and John Arnold Foundation, the Peterson Center on Healthcare and the Gary and Mary West Foundation) to address generic drug shortages and the high costs of vital medicines. Today, Civica membership includes over 50 health systems, representing more than 1,200 U.S. hospitals (over 30% of all licensed hospital beds in the country). Kaiser Permanente is the most recent health system to join Civica.

Civica was primarily created to improve the resiliency of the supply of essential medicines used in hospitals daily, often for critical care. The drugs we make are not those with the highest return on investment. Rather, they are the ones that are identified and prioritized by our health systems – by doctors and pharmacists on the front lines – as the medications most important for high-quality patient care. Civica’s members have also identified generic medications that are excessively priced, such as daptomycin, where Civica lowered significantly the market price.

The Civica model brings together hospital systems and drug manufacturers to work collaboratively, ensuring both stable and fairly priced generic drugs for hospitals and predictable volumes for manufacturers. Key elements of the model include:

- Hospital systems join Civica, allowing them to purchase drugs in predetermined volumes at transparent and stable prices. Member health systems prioritize the medications needed to reduce shortages for patients and identify the volume requirements for their hospitals.
- Civica conveys this information to its manufacturing team or trusted manufacturing partners – those with a history of producing high-quality products. Manufacturers commit their production capacity based on long-term projected volumes of medications identified by the health systems.
- As a result, patient care improves as hospitals receive a reliable supply of the essential generic medications.

Because its specific mission is to create a robust, high-quality supply of essential medicines, several features of the Civica supply chain model may have lessons for the larger U.S. system, including:

- Long-term purchase commitments allow Civica and suppliers to invest in quality systems
- Use of backup suppliers and maintenance of a reserve stock averaging at least six months’ supply
- A preference to purchase medicines made in the U.S. where possible, followed by other highly regulated markets, followed by India and avoiding Chinese ingredients where possible in our drugs due to quality concerns
- Entrusting those on the front lines – hospital physicians and pharmacists – to prioritize the medications Civica makes, based on their experiences day-to-day or in times of crisis like the pandemic

Below are highlights of Civica’s three-pronged manufacturing strategy, as well as its manufacturing partners to date:

- Working with multiple generic drug manufacturers that have the US FDA approved manufacturing facilities and capacity to produce generic drugs under Civica’s National Drug Code, allowing manufacturers to re-enter the market or increase existing capacity.
 - Hikma
 - Novartis Sandoz
 - Xellia
 - Exela
 - + five others not yet announced publicly
 - + others in ongoing negotiations
- Developing Abbreviated New Drug Applications (ANDAs) for essential generic drugs and working with contract manufacturing organizations to produce Civica medications.
 - Patheon / Thermo Fisher Scientific
- Building Civica manufacturing facilities using Civica’s ANDAs.
 - In response to COVID-19 and in preparation for future pandemics, Civica is part of a [US government funded partnership](#) to develop end-to-end advanced manufacturing in the United States. Civica’s role is to build, own and operate a finished dosage sterile injectable manufacturing plant to supply the US Strategic National Stockpile as well as its health system members with essential medicines.

What else makes Civica unique?

Typical Generic Drug Supply Chain	Civica Rx Generic Drug Supply Chain
Often sources drug ingredients from low-cost markets – especially China	Sources drug ingredients from mostly US and European suppliers - 93% of our Active Pharmaceutical Ingredients are primary sourced from countries other than China (37/40)
Relies heavily on sterile injectable drug manufacturers from low-cost market such as India and China	Relies mostly on sterile injectable drug manufacturers in the US and Europe - 88% of our medicines are manufactured in US, Canada and Europe (35/40)
Frequently relies on one or two manufacturers for drug ingredients and finished drugs	Ensures redundant manufacturing capabilities for drug ingredients and finished drugs
Little or no transparency in labeling regarding manufacturing location	Labeling includes manufacturer location
Operates with “just-in-time” inventory, less than 30 days, of essential medications	Operates with several months of inventory of essential medications for its member hospitals
Prices for essential medications can fluctuate wildly from very low to extremely high	Prices are fair and stable with little fluctuation for member hospitals
Drug supply chain often disrupted due to shortages	Little or no disruption to drug supply chain due to shortages, including during COVID-19
To ensure patient care, hospitals hoard essential medications, leaving little or no inventory for others	Ample supply of essential medicines are guaranteed for member hospitals, so no need to hoard them to ensure proper patient care
Hospital staff scramble to find alternative medicines, taking time away from patients and adding to overall cost of care	No need for scrambling so patients receive optimal care with no additional costs incurred

In summary, Civica is committed to transparency and offers fair and sustainable prices to its member hospitals. It also ensures it has dedicated manufacturing capacity for the medications that are most desperately needed in hospitals across the country through redundant manufacturing and a strategic safety stock of medications to help prevent drug shortages in the future.