

14 Jan 2022 | Analysis

Generics Industry At The Forefront In War Against COVID-19 In 2021

As Companies Innovate, Collaborate And Donate To Provide Relief

by **Akriti Seth**

As the COVID-19 pandemic continued in 2021, the off-patent industry stepped in to provide relief in a variety of ways, whether through securing supplies of essential medicines or helping to manufacture and distribute newly-developed treatments.

As countries were hit by COVID-19 in different phases in 2021, we saw the generics industry step up to provide relief, launch newer treatment options, keep up the supply of essential medicines to meet the market demand as patient needs increased throughout the pandemic, even amp up the manufacturing and distribution of critical COVID drugs like favipiravir, remdesivir and tocilizumab as well as COVID-19 vaccines.

Some contributions from the generics industry involved collaborating on developing and producing versions of newly-developed coronavirus treatments. In late 2021, Bangladesh's [Beximco Pharmaceuticals Ltd.](#) launched the world's first generic version of the molnupiravir oral treatment for COVID-19, to broaden access and affordability of COVID-19 treatment (Also see "[Beximco Launches World's First Molnupiravir Generic](#)" - Generics Bulletin, 9 Nov, 2021.)

This came shortly after developers [Merck & Co., Inc.](#) and [Ridgeback Biotherapeutics LP](#) partnered with the Medicines Patent Pool to increase access to the oral antiviral COVID-19 drug in 105 low- and middle-income countries. (Also see "[The MPP And Merck Partner For Molnupiravir In Lower-Income Countries](#)" - Generics Bulletin, 28 Oct, 2021.)

Earlier in the year, in a joint effort, India's [Cipla Limited](#), [Dr. Reddy's Laboratories Ltd.](#), [Emcure Pharmaceuticals Pvt Ltd.](#), [Sun Healthcare Group](#) and [Torrent Pharmaceuticals Ltd.](#) had entered into a collaboration agreement to conduct clinical trials for molnupiravir. Furthermore, the

companies decided to jointly sponsor, supervise and monitor the clinical trial of the drug. (Also see "[Indian Leaders Begin Unique Collaboration On Molnupiravir](#)" - Generics Bulletin, 1 Jul, 2021.)

Another newly-developed COVID-19 treatment, [Pfizer Inc.](#)'s Paxlovid, was also licensed to the Medicines Patent Pool in late 2021, with the agreement covering 95 countries representing about 53% of the world's population, including all low- and lower-middle-income countries as well as some upper-middle-income countries in sub-Saharan Africa. (Also see "[Pfizer And MPP Sign Deal For Generics Of COVID-19 Candidate Paxlovid](#)" - Generics Bulletin, 17 Nov, 2021.)

Meanwhile, taking innovation to the next level, biosimilars developer [Celltrion](#) in 2021 launched a novel monoclonal antibody treatment for COVID-19, CT-P59 regdanvimab, in South Korea – that helped to rapidly address ongoing outbreaks. (Also see "[Celltrion's COVID-19 Treatment Regdanvimab Is Approved In Korea](#)" - Generics Bulletin, 21 Sep, 2021.) The product has also been endorsed by the European Medicines Agency.

The need for critical COVID medicines also paved the way for several partnerships between big names from both the generics and brand industry. These partnerships played a pivotal role in providing relief during the pandemic.

For example, early in 2021 Pfizer partnered with Premier Inc's ProvideGx program to supply five essential injectable drugs to healthcare providers in the US, including some medications that are necessary as part of COVID-19 treatments. (Also see "[Pfizer Partners With Premier To Supply Critical Injectables](#)" - Generics Bulletin, 28 Jan, 2021.)

Meanwhile, in the US, a group of 11 Premier Inc member health systems, a group purchasing organization, responded to pandemic-exacerbated supply difficulties by investing in generic injectables specialist Exela Pharma Sciences to garner uninterrupted supply of 19 pharmaceutical products, including several shortage-hit generic injectables. (Also see "[Premier Invests In Exela To Procure Shortage-Hit Generic Injectables](#)" - Generics Bulletin, 10 Sep, 2021.)

India's Challenging Second Wave

As India struggled with a second wave of COVID-19 during April-May 2021, patients repeatedly flagged the shortages of COVID drugs like remdesivir and favipiravir.

In the peak of India's second wave, the generics industry rose to the challenge as [Gilead Sciences, Inc.](#) announced measures to help Indian remdesivir licensees to rapidly scale up production in response to the increase in COVID-19 cases in India.

(Also see "[Gilead Scales Up Remdesivir Production To Meet Indian Demand](#)" - Generics Bulletin, 27 Apr, 2021.)

Industry Steps Up To Help India Through Second Wave

By [Akriti Seth](#)

The company also donated at least 450,000 vials of the branded Veklury version “to help address the immediate needs of Indian patients.”

Meanwhile, to make remdesivir more affordable in India, [Zydus Cadila](#) slashed the price of its brand of remdesivir, Remdac, from INR2800 (\$37.40) to INR899 for a 100mg lyophilized injection.

And both Dr Reddy’s and Stelis Biopharma, the biopharmaceutical division of [Strides Pharma Science Limited](#), partnered with the Russian Direct Investment Fund to produce and supply the Russian Sputnik V vaccine to India (*see sidebar*).

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As India sees a consistent rise in daily cases and deaths due to COVID-19, the off-patent industry is stepping up to make drugs affordable and available. Zydus Cadila is seeking approval for virafin, while Natco has applied for molnupiravir approval. Vaccine production and availability has also come under focus.

[Read the full article here](#)

To help India through the second wave, [Biocon, Ltd.](#) launched a dedicated 24x7 pandemic-care helpline to give information on the availability of its COVID-19 products and to handle the pandemic related queries.

Working With Governments

With a view to “co-operate and collaborate,” companies also worked with governments in 2021 to provide relief to populations at large during the pandemic. [Novartis](#)’ Sandoz division provided generics and biosimilars in Vietnam at-cost for the treatment of severe COVID-19 symptoms, under a memorandum of understanding signed between Novartis and Vietnam’s Ministry of Health. (Also see "[Sandoz Provides COVID Portfolio At Cost In Vietnam](#)" - Generics Bulletin, 2 Dec, 2021.)

In the US, [Endo International plc](#)’s Par subsidiary entered into an agreement with the government to expand its sterile fill-finish manufacturing production capacity and capabilities at its Rochester, Michigan plant to support national pandemic preparation efforts, as the US government agreed to fund approximately \$90m of the program’s expected total cost of around \$120m. (Also see "[Endo Partners With US Government On Critical Medicines](#)" - Generics Bulletin, 25 Nov, 2021.)

To supply vaccines to the local population, Beximco imported the Oxford-AstraZeneca COVID-19 vaccine from the Serum Institute of India to Bangladesh, under the contract between India and Bangladesh. (Also see "[Aurobindo Announces Vaccine Partnership For India](#)" - Generics Bulletin, 7 Jan, 2021.) And Alvogen and sister company [Alvotech](#) announced a donation of to UNICEF to help get COVID-19 vaccines to over 90 low-and-middle-income countries, while [Hikma](#) also contributed millions of dollars’ worth of medicines to support those facing challenges

caused by the pandemic. (Also see "[Alvogen Companies Donate To Support COVID Vaccines](#)" - Generics Bulletin, 16 Mar, 2021.)

Meanwhile in Australia, the country's Generic and Biosimilar Medicines Association recently welcomed the passage of legislation aimed at increasing local stocks and mitigating shortages, against the backdrop of supply chain disruption caused by the COVID-19 pandemic, based on a strategic agreement between the off-patent industry and the government that is due to start in mid-2022. (Also see "[Australian Body Welcomes Passage Of Shortages Law](#)" - Generics Bulletin, 3 Dec, 2021.) This follows enhanced collaboration between the generics industry and brand industry in Australia to help secure supplies during the pandemic. (Also see "[Australian Body Confirms Collaboration Conditions](#)" - Generics Bulletin, 13 Dec, 2021.)

"There should be a dialog between the regulators, the policymakers and the industry, and this dialog is very critical," insisted industry voice Sanjay Singh – CEO of Genova Biopharmaceuticals, as Indian regulatory and industry bodies called for open dialog with policymakers while discussing India's role in helping the world deal with the pandemic. (Also see "[Indian Regulatory And Industry Bodies Call For Open Dialog With Policymakers](#)" - Generics Bulletin, 28 Nov, 2021.)

Prominent Industry Voices

During 2021, we also saw prominent industry figures voice their opinion on how experience gained during the pandemic can be used to improve medicines systems overall.

Kiran Mazumdar-Shaw, executive chairperson of Biocon, noted that "the concept of emergency use approvals, rolling reviews and parallel phase one, phase two, phase three clinical development have all played a significant role in regulatory acceleration," pointing to some of the changes brought by the pandemic in regulatory processes in India. (Also see "[Indian Regulatory And Industry Bodies Call For Open Dialog With Policymakers](#)" - Generics Bulletin, 28 Nov, 2021.)

Mazumdar-Shaw added that "we should not lose this opportunity to basically bring in regulatory reforms that will enable larger R&D, investments, and hopefully prolific innovation, because of accelerated regulatory timelines."

Meanwhile, Phlow CEO Eric Edwards threw light on challenges faced by the US due to the COVID-19 pandemic and said, "We need domestic manufacturing for key essential medicines in case of supply chain disruptions in the future." (Also see "[Critical To Bring Back Domestic Manufacturing Of Key Essentials' Insists Phlow CEO](#)" - Generics Bulletin, 1 Sep, 2021.) Referring to an expected boom of off-patent medicines in the US, Edwards said, "I think you will be seeing a resurgence of manufacturing for generics, biosimilars and other affordable medicines right here in the US." (Also see "[Phlow CEO Reveals Possible Partnerships With 'Global Generics](#)"

[Manufacturing Companies](#)" - Generics Bulletin, 3 Sep, 2021.)

And Rebecca Guntern, Medicines for Europe's president, recently insisted that an immediate opportunity exists for generics and biosimilars to become more central to European healthcare policy and play a key role in helping the region to rebuild as it moves out of the COVID-19 pandemic. (Also see "[Central Role For Industry Beckons As Europe Rebuilds After COVID](#)" - Generics Bulletin, 22 Oct, 2021.)

Mining Pandemic Led Opportunities

The crisis birthed by COVID-19 also paved the way for billionaires like Mark Cuban to launch a new generics venture, the Mark Cuban Cost Plus Drug Company, as the company admitted that the pandemic accelerated the launch. (Also see "[Mark Cuban 'Very Involved', Insists Generics Company CEO](#)" - Generics Bulletin, 28 Jan, 2021.)

As a part of its COVID-19 response effort, the Bill & Melinda Gates Foundation committed up to \$120m to support the development and manufacturing of generic versions of molnupiravir, for lower-income countries, in partnership with Merck & Co. (Also see "[Bill & Melinda Gates Foundation Commits \\$120m For Molnupiravir In Lower-Income Countries](#)" - Generics Bulletin, 22 Oct, 2021.)

To support the social and emotional needs of families across generations during the COVID-19 pandemic, some companies tried to provide relief in innovative ways. In an instance, Viartis ran a Sesame workshop "to help children and caregivers manage social and emotional needs during the holiday season and beyond," by launching Sesame workshop animations and materials in English, Spanish, Hindi and Portuguese, across six continents. (Also see "[Aurobindo Announces Vaccine Partnership For India](#)" - Generics Bulletin, 7 Jan, 2021.)

As the global COVID-19 pandemic continues into its fourth calendar year following its beginnings in late 2019, the off-patent industry will remain at the heart of efforts to support healthcare systems and increase access to key treatments.

In the earliest days of 2022, efforts have already been seen to make molnupiravir generics available in India (Also see "[Wave Of Molnupiravir Generics In India Amid Early Physician Cheer](#)" - Generics Bulletin, 5 Jan, 2022.), while Beximco has once again broken ground for the industry by launching the first generic version of Paxlovid, in Bangladesh. (Also see "[Beximco Delivers First Cut-Price Generic Paxlovid](#)" - Generics Bulletin, 4 Jan, 2022.)