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Generics Industry Counts Cost Of Stormy Second Quarter

Teva, Sandoz And Mylan Saw Q2 Industry Downturn Coming

by **Akriti Seth**

As the global generics industry had predicted, the unexpected growth seen in the first quarter of 2020 due to forward buying caused by COVID-19 levelled off in the second quarter. However, a few companies managed to report a "mixed" second quarter or a positive first half for 2020, even after experiencing challenges, such as operational interruptions, posed by the pandemic.

The second quarter of 2020 has balanced out the unexpected extraordinary first quarter seen by the global generics and biosimilars industry, as companies almost without exception experienced a drop in sales. The most common reasons cited for the poor sales seen across the industry in the second quarter of 2020 have been reduced visits to physicians, fewer new prescriptions and a slow return to regular healthcare activities due to the COVID-19 outbreak.

Most of the companies that saw reversals of forward buying in the second quarter of 2020 had predicted a levelling off of sales, after demand for medicines was boosted in the first quarter due to stockpiling and the hoarding phenomenon induced by the coronavirus crisis, as well as advance prescribing. (*Also see "Generics Industry Experiences Extraordinary First Quarter Due To COVID-19 Crisis" - Generics Bulletin, 7 Jul, 2020.*) However, a few companies continued to ride the wave of increased sales.

While some companies like Hikma, Towa and Dr Reddy's reported mixed results, with single-digit increases in generics sales during the quarter, a few others adjusted their annual outlooks for the remainder of the financial year. And a series of companies that had performed poorly during the first quarter of the year saw sales stabilize and return to normal or in line with its expectations.

While the first quarter may have been unexpectedly extraordinary for the global generics industry, the second quarter was a setback even for giants like Teva, Sandoz and Mylan.

Teva, Sandoz And Mylan Saw It Coming

Experiencing lower generics sales in all regions, [Teva Pharmaceutical Industries Ltd.](#)'s second-quarter sales fell in North America by 2% to \$923m and in both Europe and international markets by 13% to \$737m and \$426m respectively. ([Also see "Teva Sees COVID Sales Correction"](#) - Generics Bulletin, 7 Aug, 2020.)

"The lower generics and OTC sales in Europe and international markets were in line with our expectations, after the unusually high demand seen in the prior quarter due to the initial response to the pandemic," said Kåre Schultz, Teva's president and CEO.

The Israeli company explained that it had seen "a \$200m swing factor in Europe" across the first and second quarters. Schultz said, "In the first quarter, we probably sold \$200m more. We can see [that] now when we analyze Q2 patient level hoarding and stockpiling of products. And that means in the second quarter, we sold \$200m less."

"Demand is still lower, but we have seen signs of normalization towards the end of Q2." - Sandoz

Novartis' [Sandoz Inc.](#) reported an 11% downturn in Europe to \$1.13bn in the second quarter, which was outpaced by a 21% decline in the US to \$508m. ([Also see "Biosimilars Will Lift Sandoz Following Q2 Sales Slump"](#) - Generics Bulletin, 22 Jul, 2020.) Apart from citing "significant disruption to practices, limiting patient access to treatments" as a main cause of the slump, Sandoz said that "the COVID impact is difficult to model but we believe Q1 forward purchasing effectively reversed in Q2."

"Demand is still lower," Sandoz said, "but we have seen signs of normalization towards the end of Q2."

The company's sales dropped by 7% to \$180m in Canada and Latin America. However, Sandoz did see an uptick during the quarter that came from its combined Asia, Africa and Australasia segment, where sales improved by 2% to \$341m.

[*Mylan Pharmaceuticals Inc.*](#) also saw a drop in sales in its Europe and the rest of the world markets in the second quarter of 2020 due to COVID-19. ([*Also see "Mylan Sees COVID-19 Impact On Sales"*](#) - Generics Bulletin, 11 Aug, 2020.) The company said that the while volumes were hit by COVID-19, unfavorable currency effects contributed even further to the declines.

Pointing to the first-half figures overall, rather than the quarterly numbers, Mylan CEO Heather Bresch commented, “we believe our results from the first half of the year better represent the underlying performance of the business due to the fact that any COVID-19-related gains in Q1 were more than offset by the negative impact of the pandemic in Q2.”

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US Players See Reversals

Similar trends were seen across the industry, with a common theme emerging among major US generics players.

[*Amneal Pharmaceuticals, Inc.*](#) reported generics sales of \$307m in the second quarter of 2020, compared to \$353m in the first quarter. ([*Also see "Amneal Plans Eight More 'High Value' Launches"*](#) - Generics Bulletin, 13 Aug, 2020.) President and co-CEO Chirag Patel said, “as we expected, COVID-19 had a temporary negative effect. Demand for some products dipped as patients delayed procedures and physician’s office visits.”

Reporting a 1% drop in generics sales to \$216m in Q2 2020, [*Endo International plc*](#) marked a step down from the \$251m of generics sales reported in the first quarter of 2020. ([*Also see "Endo's Generics Face Competitive Pressures"*](#) - Generics Bulletin, 20 Aug, 2020.)

[*Akorn, Inc.*](#) saw its revenue drop by 32%, or \$58m, to \$120m for the second quarter of 2020. ([*Also see "Q2 Results: COVID-19 Kicks Akorn While It's Down"*](#) - Generics Bulletin, 24 Aug, 2020.) The firm said that “the decrease in the gross profit percentage was principally due to the impacts of the COVID-19 pandemic, which included unfavorable volume and product mix, unfavorable manufacturing variances, along with increased employee retention costs.”

Japan’s [*Sawai Pharmaceutical Co., Ltd.*](#) reported sales from its US Upsher-Smith unit that fell by 6% to ¥8.79bn (\$82.9m) in the firm’s financial first quarter ended 30 June ([*Also see "Sawai's Upsher-Smith Takes Aim At US Corticotropin Opportunity"*](#) - Generics Bulletin, 11 Aug, 2020.), with the company attributing the decline “to lower customer orders in May and June after a significant inventory build in March and April” in response to COVID-19.

And [*Lannett Company, Inc.*](#)’s group sales declined by 16.7% to \$545.7m in its financial year ended 30 June 2020. ([*Also see "Lannett Confident Of \\$1bn In Sales By 2025"*](#) - Generics Bulletin, 27 Aug, 2020.)

Global Rebound Seen After Initial Spike In Demand

Major off-patent companies across the globe had to cope with a similar dip in the second quarter.

India's [*Sun Pharmaceutical Industries Ltd.*](#) was one of the few that plunged into a loss for the quarter ending 30 June 2020. ([*Also see "Sun Loses Shine Amid Testing Times In US"*](#) - Generics Bulletin, 4 Aug, 2020.) The company's management said that the drop in business reflected the impact of the COVID-19 pandemic and consequent lock-down across multiple markets. Sun Pharma's overall consolidated sales for the quarter declined by 10% to INR74.67bn (\$997m), while its net loss stood at INR16.56bn.

Meanwhile, Lupin's profit dipped to INR1.07bn compared to INR3.9bn in the fourth quarter and INR3.03 in the first quarter of fiscal 2020. ([*Also see "Lupin Cuts Forecast Despite Etanercept Launch"*](#) - Generics Bulletin, 13 Aug, 2020.)

Smaller players were similarly affected. Despite predicting in future "a return to more normalized prescription patterns and further growth of [the drugs] that were negatively impacted by COVID-19," Australia's [*Mayne Pharma International Pty. Ltd.*](#) reported generics sales down by 21% to AUS\$253.0m (US\$169.8m) for its financial year ending 30 June 2020, as its overall sales fell by 13% to AUS\$457m. ([*Also see "Mayne's Generics Segment Sees Double-Digit Drop In Sales"*](#) - Generics Bulletin, 26 Aug, 2020.)

Mayne said that its specialty brands segment had been significantly impacted by COVID-19 mainly due to a reduction in patient visits to physicians. The company pointed out that its prescriptions were down approximately 15% across the dermatology portfolio in April and May 2020.

A Look At Annual Financial Outlook And Forecast

As the off-patent industry waits for sales to return to normal, companies have taken another look at their annual financial outlooks.

According to Mylan, overall COVID-19 recovery efforts are occurring slower than anticipated and may continue at least through the end of this year. CEO Bresch stated, "we expect that our total revenues, which absorbed a 2% net decline in the first half of the year, to have an overall similar negative impact of 2% in the second half of the year."

However, reaffirming Teva's annual financial outlook that was presented earlier this year, the firm's chief financial officer Eli Kalif insisted that the company expects to see "total revenue of \$16.6bn to \$17bn."

Meanwhile, India's [*Glenmark Pharmaceuticals Limited*](#) said it expected to see its sales stabilize in its financial second quarter ending in September, after a challenging first quarter. ([*Also see*](#)

["Glenmark 'Not Taking Foot Off Pedal' In US But Q1 Was Tough"](#) - Scrip, 19 Aug, 2020.) Chief commercial officer Robert Crockart said that "we expect from Q2 onwards to get quarter-on-quarter growth."

And Swiss contract development and manufacturing organization Siegfried expects a stronger second half for 2020. ([Also see "Siegfried Expects A Stronger Second-Half For 2020"](#) - Generics Bulletin, 27 Aug, 2020.) Noting that first-half results were "clearly affected by COVID-19," Siegfried has forecasted low single-digit percentage growth in sales in local currencies for the full year of 2020 and a slight expansion of its earnings before interest, taxes, depreciation, and amortization (EBITDA) margin.

Other firms, however, are less optimistic given the signs already observed in 2020 so far. Based on an increase in its sterile injectables segment which was "primarily driven by significant channel inventory stocking of Vasostrict (vasopressin), in anticipation of treating vasodilatory shock in patients infected with COVID-19," Endo said that its financial guidance for 2020 reflects the anticipated unfavorable impact of "significant Vasostrict channel destocking."

Some Companies Bucked The Trend

While some companies reported positive first-half results based almost entirely on the COVID-19-induced forward buying or inventory stocking, others were affected by factors like recent acquisitions, cost reduction initiatives and new investments.

Though [STADA Arzneimittel AG](#) described the second quarter of 2020 as "tough," the company welcomed an "above-market sales and earnings increase" in the first half of this year, with the firm's generics sales increasing by 12% to €833.4m (\$986m), driven by sales increases in major European markets alongside the acquisition of a product portfolio from Switzerland's Opti Pharm. ([Also see "Stada Raises Sales And Earnings But Admits 'Tough' Q2"](#) - Generics Bulletin, 3 Sep, 2020.)

[Hikma Pharmaceuticals plc](#) saw its operating profit jump by a quarter in the first half of 2020, as a lift from its injectables business helped to drive up turnover by almost a tenth. ([Also see "Hikma's First-Half Profits Leap By A Quarter"](#) - Generics Bulletin, 11 Aug, 2020.) The company said that its first-half sales and profits were ahead of its initial expectations, with operating profit rising by 25% to \$297m on sales up by 8% at \$1.132bn.

CEO Siggi Olafsson told *Generics Bulletin* that "we had a very good first half of the year. I think the key was that even in COVID, we managed to keep all the manufacturing plants open and running and we didn't miss a beat." ([Also see "Hikma Is Keeping On Top Of COVID 'Rollercoaster'"](#) - Generics Bulletin, 9 Sep, 2020.)

Meanwhile, driven by increases in its European, North American and emerging markets - offset partially by a decline in India - [Dr. Reddy's Laboratories Ltd.](#)' generics segment reported 6% year-

on-year growth with total sales of INR35.1bn for the firm's financial first quarter ended June 2020. ([Also see "Dr Reddy's International Business Makes Up For Domestic Decline"](#) - Generics Bulletin, 10 Aug, 2020.)

Dr Reddy's generics segment grew by 48% to INR3.55bn in the European market. Furthermore, the company's North American market made sales of INR17.3bn, an increase of 6%.

Anneal's generics segment reported operating profit of \$27m for the second quarter of 2020 compared to of \$5m for the prior year period. According to the company, the increase was partly due to "lower selling, general and administrative expenses as well as R&D expenses due to cost reduction initiatives and the timing of expenses in 2020 due to delayed spending as a result of COVID-19."

Despite its pessimistic full-year forecasts, Endo's sterile injectables segment saw revenues of \$319m in the second quarter of 2020, an increase of 31% compared to the second quarter of 2019. Blaise Coleman, Endo's president and CEO, said, "our sterile injectables segment delivered strong revenue growth versus the prior year as customers built significant inventory levels of products used to treat certain COVID-19 patients."

[Towa Pharmaceutical Co Ltd](#) also reported a mixed financial quarter ending 30 June 2020. ([Also see "Towa's New Overseas Business Boosted By COVID-19 Demand"](#) - Generics Bulletin, 17 Aug, 2020.) The Japanese company saw sales of ¥9.96bn for its international business, which was "above plan due to increased demand for pharmaceuticals as a result of long-term prescriptions induced by COVID-19 spread."

The company gave credit to its decision to acquire Pensa Investments generics business from Spain's Esteve, as it helped exceed expectations in Towa's quarterly results.

And India's Divi's Laboratories reported a staggering 47% growth by reporting total sales of INR17.48bn (\$234m) for its financial first quarter ended 30 June 2020, compared to turnover of INR11.93bn in the prior year period. ([Also see "Divi's Labs Grows By Almost Half"](#) - Generics Bulletin, 18 Aug, 2020.) Divi's noted that its growth came against a backdrop of the coronavirus pandemic that has both boosted demand for certain active pharmaceutical ingredients and has also resulted in supply constraints from certain regions such as China.

Supply Chain Challenges Due To COVID-19

Operational disruptions, as well as financial turbulence from the ongoing impact of the COVID-19 pandemic, has forced generics and biosimilars companies to deal with supply-chain and production disruptions, amid a host of various national containment measures put in place worldwide.

From early in the first quarter to mid-year, the need to expand manufacturing capacity was seen

throughout the generics industry due to the rise in demand for medicines, specifically antibiotics, respiratory drugs and critical medicines. Amidst the growing demand-supply gap, major companies reported facing supply chain challenges.

Sandoz CEO Richard Saynor said “this crisis is exceptional, both in how it impacts our patients and the complexity it presents to us in how we respond, because we see a demand surge combined with major supply restrictions.” ([Also see "Teva, Sandoz And Accord Take COVID-19 Action"](#) - Generics Bulletin, 2 Jun, 2020.) Sandoz reported taking measures to increase its inventory of medicines to tackle coronavirus-related supply chain issues.

Teva had also expressed concerns over production hubs like India and China that control a large part of manufacturing of raw materials and APIs. The company changed its previous production strategy to prioritize products that are more in demand. ([Also see "Teva Emerges From Restructuring Ready To Grow"](#) - Generics Bulletin, 20 Feb, 2020.)

While Amneal saw temporary disruption in its manufacturing, Siegfried reported a production interruption in its Nantong China site for two weeks in February due to general national lockdown measures.

Siegfried also recorded low manufacturing performance during the first half of 2020 because of higher absentee rates mainly from precautionary quarantine measures, individual delays within the supply chain and delayed maintenance repairs by third-party service providers.

However, the company noted that as an important manufacturer of essential pharmaceutical products, government entities in many countries granted Siegfried the status as being relevant to the healthcare system which “created the basis for the continued operation of our plants even during the crisis.”

According to [Strides Pharma Science Limited](#), the pandemic has the potential to cause significant disruption in its manufacturing operations and supply chain given that COVID-19 cases are on the rise in Karnataka, India. ([Also see "Strides Hits Pause On Stelis Injectables Investments"](#) - Generics Bulletin, 18 Aug, 2020.)

Countries also took national measures to secure the drugs supply chain. The significance of Chinese supplies to industries worldwide was highlighted during the coronavirus outbreak and global attention turned to the issue of single sources of imports for key ingredients, and securing critical medicines.

US President Donald Trump signed an executive order to enhance the security of the US pharmaceutical supply chain for essential medicines, medical countermeasures and critical inputs, and reduce its dependence on foreign manufacturers. ([Also see "'Buy American' Executive Order Receives Backlash"](#) - Generics Bulletin, 12 Aug, 2020.) Meanwhile, the Indian Pharmaceutical Alliance laid out a plan to reduce dependency on China for APIs and

intermediaries, noting that domestic manufacturers were “at risk of supply disruptions and unexpected price movements” because of their heavy reliance on Chinese exports ([Also see "Reducing Chinese API Imports Key For Indian Pharma Growth, Says IPA"](#) - Generics Bulletin, 21 Jul, 2020.).

The generics industry played a crucial role in handling of the pandemic so far and it is now preparing to be a “bridge to a vaccine.” ([Also see "New AAM Chief Sets Out Priorities"](#) - Generics Bulletin, 10 Sep, 2020.) The newly appointed CEO of the Association for Accessible Medicines, Dan Leonard, said “the COVID-19 pandemic continually demonstrates that our industry is fundamentally strong and critical to saving lives and containing costs for those stricken with the virus.”

Looking ahead, while some companies expect revenues to stabilize for the second half of the year, a few are optimistic about not only a recovery and but an upward trajectory of the company’s performance. Along with countries revisiting policies around coronavirus, the entire generics industry is also expected to go through major changes to keep up with the impact of the pandemic.