GENERICS BULLETIN
CITELINE COMMERCIAL

29 Aug 2023 | **Analysis**

Generics Bulletin Explains: The Changing US Generics Market

Price Pressures Are Abating Amid Portfolio Pruning, Market Exits And Shortages

by David Wallace

After a couple of years of heavy downwards pressure on US generics prices, prominent off-patent companies have pointed to a change in the pricing environment as several factors combine to reduce price erosion. Meanwhile, some firms are benefiting from first generic launches as others exit the market altogether, while injectables shortages continue to loom large.

Robert Califf, commissioner of the US Food and Drug Administration, recently summarized in straightforward terms the disconnect between the public perception of high drug prices and the realities for the off-patent industry by stating that innovator prices "are too high," while for the generics industry "a lot of the prices are too low."

"What I mean by that," Califf explained, in widely reported comments made at an Alliance for a Stronger FDA event, "is that the price has been driven down below the cost of manufacturing and distributing the drug. And we have an industry which is continuing to leave the US because it's not viable to run the business."

Califf's comments reflect the experience of generics firms over the past few years, with the US generics industry in 2021 and 2022 seeing a fresh period of instability.

Generics Industry Braces For New Wave Of Price Pressure

Double-digit price erosion has been

GENERICS BULLETIN
CITELINE COMMERCIAL

driven by multiple factors, including purchaser consolidation, cost pressures exacerbated by the COVID-19 pandemic, increasing FDA approvals for older generics in competitive markets and relatively few FDA approvals for new generics (*see sidebar*).

"The competitive pricing environment we currently find ourselves in has intensified beyond historical norms and our recent expectations," one generics industry CEO said in early 2022, referring to this as an "industry-wide phenomenon." (Also see "*Lannett: Pricing Pressure Has 'Intensified Beyond Historical Norms'*" - Generics Bulletin, 7 Feb, 2022.)

By David Wallace

25 Apr 2022

With pricing pressures already creeping up in recent years, 2022 is set to see the generics industry caught in the middle as prices are further squeezed while costs continue to rise. As major players prepare to announce their first-quarter financial results, *Generics Bulletin*looks at views from industry leaders on how these pressures are affecting their businesses, and how they...

Read the full article here

Former Hikma chief Siggi Olafsson at the time explained the typical peaks and troughs of pricing in the US generics industry. "I believe – and I've been doing this now for just over 20 years – the pricing in the US is cyclical," he said. "You usually have at maximum two challenging years, and then you usually have three to four very decent years."

"We had 2016 and 2017, which were challenging years for pricing; we had 2018, 2019 and 2020, quite good years; [then] we had a change of the storm a little bit in 2021; and...double-digit pricing [erosion] for 2022." (Also see "*Hikma Warns Of Renewed Pricing Pressure On US Generics*" - Generics Bulletin, 3 Mar, 2022.)

Pricing Pressures Recede In 2023

But if 2021 and 2022 were the latest "challenging years" for the generics industry, then 2023 has showed clear signs of the tide turning, with multiple leading off-patent industry players recently pointing to a gentler operating environment compared, at least compared to the past couple of years.

Speaking as Teva reported its second-quarter results in August, the firm's executive vice president for North America commercial, Sven Dethlefs, indicated that "the US generics price decline has indeed slowed down over the last quarters."

"If you look at the pure core generics business that Teva has in the US, we actually had six very stable quarters now, which was also supported by the slowdown in price decline," Dethlefs said.

From his perspective, this was "not driven by a change in price bidding on the side of wholesalers or on the side of buying groups," but supply chain disruptions and supply discontinuities from firms in the sector had helped to slow down price erosion in general.

"What we also notice is that not only Teva but also other companies are looking into portfolio consolidation," Dethlefs pointed out. "And if you do that, typically it supports the price decline slowdown."

"And then we've seen not too many large generic launches, which is the third factor typically influencing price decline," the executive observed. "And for that reason, we overall see a stable situation at the moment, and we have to see if this continues over the next quarter. So far, we have no indication for a change." (Also see "*Teva Outlines US Opportunities Amid North American Decline*" - Generics Bulletin, 3 Aug, 2023.)

Meanwhile, Sandoz CEO Richard Saynor was asked earlier in the year about comments made by Sandoz parent firm Novartis in late 2022 that the small-molecule generics market had reached a "bottom." (Also see "*Sandoz: US Oral Solids And Injectables Have Reached Bottom*" - Generics Bulletin, 26 Aug, 2022.)

"We've been saying that for decades," he acknowledged, suggesting that the recent slowdown in price deflation was likely "more a reflection of the instability of supply issues from the industry, rather than necessarily the willingness of payers to recognize they need to pay more."

"I think this is a temporary blip with inflation, and supply constraints for all sorts of reasons," he suggested. "Sites in India have been closed down by the FDA, [there have been] active pharmaceutical ingredient issues, disruptions in the network. So there's a whole bunch of factors. And I think also coming on the back of COVID, where a lot of demand was suppressed, and inventory got built up, everyone cut resources." (Also see "*Sandoz's Saynor Reflects On Industry Challenges*" - Generics Bulletin, 3 Mar, 2023.)

> ***"We have seen price stabilization over the last several quarters in North America, which we have not seen for a few years."***

The third generics industry giant, Viatris, has also recently offered its take on the changing nature of the US market.

"We always knew that the pricing is [based on] two factors in effect: supply and demand, and portfolio mix," outlined Viatris president Rajiv Malik during the firm's recent Q2 results call. On the former, he commented, "yes, the market is seeing some disruption, some hiccups and it may go a little bit further in that direction, before it gets better." But because of supply disruptions, "and because of our diversity," he said, "we have seen price stabilization over the last several quarters in North America, which we have not seen for a few years."

On portfolio mix, Viatris had worked "diligently to move away from commodities, into more diversified, complex products, and that's giving the underlying stability of the mix in the US," Malik suggested. So "we see the market conditions improving in North America as far as the generics are concerned." (Also see "*Viatris: Watch Out For Potential Complex Injectable Launches In 2023*" - Generics Bulletin, 14 Aug, 2023.)

One leading company that has been particularly hard-hit by generics pricing pressure in the US is Hikma, which saw its generics business take a big dive last year, but has more recently pointed to a rosier future for US generics (*see sidebar*).

In general, Hikma recently stated, "we have seen a reduction in price erosion and we have been able to increase volumes across the portfolio," with the company "addressing market disruptions and winning awards for new business across."

CEO Said Darwazah pointed out that "the challenging market conditions we experienced in 2022 are starting to ease with an improvement in retail generics volume and pricing levels." And "what's interesting to also note is that we are seeing a decline in US-based manufacturers," Darwazah said, for which "volumes have nearly halved over the last six years."

Ultimately, he summarized, "we have seen a reduction in the level of price erosion and we have been able to increase volumes across our portfolio," demonstrating that "our business has proven to be strong enough to weather the bad storm we saw in 2022."

Hikma Sees Signs Of A Bounceback For Generics

By David Wallace

28 Apr 2023

After a tough 2022 that saw Hikma suffer an 18% drop in generics sales – albeit mostly offset by growth in the firm's injectables and branded divisions – the company has announced fresh forecasts for 2023 that suggest the generics segment will bounce back with growth of a fifth.

Read the full article here

New Launches Lift Some Players As Others Drop Out

Another factor influencing the fortunes of US generics players is their ability to deliver on key pipeline assets, especially first generics.

GENERICS BULLETIN
CITELINE COMMERCIAL

While the FDA has received some criticism in the past for approving lots of abbreviated new drug applications for products where generic competition exists – but being slower to approve new first-time ANDAs – the US market has nevertheless seen a fairly steady stream of first generics so far this year.

Early 2023 saw the debut of Xyrem (sodium oxybate) and Aubagio (teriflunomide) generics in the US, with an expected launch of rivals to Vyvanse (lisdexamfetamine) also just around the corner (*see sidebar*). (Also see "*Hikma Delivers On Authorized Xyrem In US*" - Generics Bulletin, 3 Jan, 2023.) (Also see "*Sandoz, Accord Confirm First US Aubagio Generics, As Settlement Day Arrives*" - Generics Bulletin, 14 Mar, 2023.)

Vyvanse Generics Get Green Light To Enter US

By David Wallace

29 Aug 2023

One of 2023's most significant loss-of-exclusivity opportunities for the generics industry has come to pass, after the US FDA approved more than a dozen rivals to Takeda's blockbuster ADHD treatment Vyvanse.

Read the full article here

And more recently, major respiratory brands like Symbicort (budesonide/formoterol) and Spiriva HandiHaler (tiotropium bromide inhalation powder) have fallen to generic competition. (Also see "*Viatris Debuts US Symbicort Rival*" - Generics Bulletin, 31 Jul, 2023.) (Also see "*Lupin Rolls Out Spiriva Generic In US, Looks To Take Back From Respimat*" - Generics Bulletin, 21 Aug, 2023.)

However, this year has also seen other generics players suffer and even drop out of the market altogether. Struggling Akorn went out of business in early 2023 (Also see "*Questions Asked After Akorn's Sudden Shutdown*" - Generics Bulletin, 6 Mar, 2023.); Lannett recently emerged from Chapter 11 bankruptcy proceedings (Also see "*Lannett Gears Up For Chapter 11 Bankruptcy, Lenders To Take Ownership*" - Generics Bulletin, 2 May, 2023.); and Mallinckrodt has just announced that it expects to enter a further bankruptcy process of its own after already going through the process in 2020. (Also see "*Mallinckrodt Files For Chapter 11 Bankruptcy Protection*" - Generics Bulletin, 13 Oct, 2020.)

Some firms like Cipla – one of several large Indian firms with a major stake in the US generics market – have cited this thinning market as one of the reasons for recent success in the US. Global CEO Umang Vohra explained that a combination of factors was driving Cipla's growth in the US, with "price compression" now lesser than before and "a large number of US companies either amalgamating, merging or going bankrupt. That is eliminating certain number of people in the system." (Also see "*Cipla Rides High Amid US Market Shakeout*" - Generics Bulletin, 14 Aug, 2023.)

Vohra also suggested that some buying programs in the US were now focused on "buying for

sustainability versus buying necessarily for price." Sustainability "could be sustainability of environment, sustainability of supply," the CEO outlined. "So, these programs are fairly active considering the shortage situation right now. And I think that creates an opportunity in some of these segments."

US Shortages Exacerbated By Pfizer Tornado Damage

Shortages are another constant factor in the US market, but in recent months there has been particular concern over the US injectables supply chain after a major Pfizer plant was damaged by a tornado (*see sidebar*).

Rocky Mount, a former Hospira facility in North Carolina, is one of the largest sterile injectables manufacturing sites in the world, producing around a quarter of Pfizer's sterile injectables – representing nearly 8% of those used in US hospitals.

Citi Research recently estimated that it could take four or five months for Pfizer to get operations back to normal at the site, but noted that the prevalence of supply disruptions in the US injectables market in general meant that buyers usually had back-up options available for most products, meaning that other suppliers could benefit from Pfizer's misfortune.

Pfizer Rallies To Fix Tornado Damage At Key Injectables Plant

By David Wallace

24 Jul 2023

In the aftermath of tornado damage to Pfizer's US Rocky Mount sterile injectables plant, the company has set out relief efforts while acknowledging the "critical role" the facility plays for the US healthcare system.

Read the full article here

Hikma, one of the biggest generic injectables suppliers by volume in the US, was recently asked outright whether it stood to gain from shortages caused by the damage at Rocky Mount. The firm's injectables chief and soon-to-be-CEO Riad Mishlawi said "we did communicate with a lot of our customers that if they face any shortages that we'll be willing to step in," but said that so far "we haven't really seen a substantial uptake right now or increase in demand," while "the US Food and Drug Administration doesn't seem like it is panicking [and] customers are not panicking."

Viatris was also asked about Rocky Mount, with the firm's president Malik commenting that "from the drug shortages point of view, we do have some overlap products with Pfizer's portfolio coming out of the Rocky Mount facility," and "if there's a need, we will step up."

Other smaller players could also stand to benefit. Jeffries analysts recently suggested that Amphastar – which has been on something of a roll lately (Also see "*Amphastar Beats The Street*

For Third Consecutive Quarter" - Generics Bulletin, 15 Aug, 2023.) – could play a significant role in addressing nationwide drug shortages, "especially regarding products used in the hospital setting."

And Amneal also recently indicated that it spied opportunity from shortages in general in the US injectables market. "Over the last few years, we have doubled our injectables capacity," said co-CEO Chintu Patel during the firm's second-quarter results call. "At the same time, the overall injectables market continues to face chronic supply shortages."

"As we look at our commercial portfolio and pending abbreviated new drug applications, 16 products are on the FDA shortage list with an additional 12 in our pipeline," Patel observed. "Amneal is well-positioned with our expanded supply chain and capacity to help address drug shortages in the US." (Also see "*Amneal Submits Modest Guidance Raise Following Strong Second Quarter*" - Generics Bulletin, 11 Aug, 2023.)

AAM Calls For Holistic Approach To Address 'Increasing Fragility'

Finally, taking a more industry-wide perspective on shortages, US generics industry body the Association for Accessible Medicines recently released a *white paper on shortages causes and solutions* that tied the issue not only to the pricing pressures of recent years, but also to regulatory and manufacturing challenges.

It said the US government should act to reduce shortages by ensuring speedier resolution of regulatory issues like quality problems and providing for higher, more stable pricing. (Also see "*AAM Calls For Congress And FDA To End Shortages By Easing Up On Generics Quality, Pricing*" - Generics Bulletin, 7 Jul, 2023.)

"At their core, drug shortages reflect challenges to the long-term sustainability of generic medicines," the AAM summarized. "While each drug shortage is unique, most stem from the increasing fragility of the generic drug market."

This instability was often caused by market and pricing factors that undermined the sustainability of generic manufacturing, along with government policies that "compound challenging market dynamics due to unpredictable reimbursement or administrative burdens," the AAM suggested, while "regulatory and manufacturing challenges place additional burdens on generic manufacturers such as delaying the supply of materials to manufacture."

"The result is a strain on supply chains and providers left without sufficient supply for patients. As FDA commissioner Robert Califf recently noted, 'we have got to fix the core economics if we're going to get this situation fixed'."