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Generics Industry Braces For New Wave Of Price Pressure

US Price Erosion Set For Double-Digits; Pricing And Costs Bite In Europe

by David Wallace

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 can be expected to play out.

Low pricing has always been something of a double-edged sword for the generics industry. While offering cheaper alternatives to branded products and allowing expanded access to medicines are fundamental components of the off-patent sector's value proposition, heavy price pressures can create an environment in which generics businesses operating on already thin margins are simply no longer sustainable. This can threaten to force certain products or suppliers out of the market entirely, reducing competition rather than enhancing it.

The generics industry – especially in the US where a limited number of buyers control much of the market – has tended to see this tension express itself as a cycle of rising and receding pricing pressures, where intense periods of severe downward pressure on prices for suppliers eventually ease, albeit only temporarily.

Unfortunately, all indications are that the generics industry is now in a period where pricing pressures are once again on the rise, against a backdrop of increasing costs across numerous aspects of business, and as part of a larger context in which healthcare systems are facing their own financial pressures as they recover from the COVID-19 pandemic.

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> *"The competitive pricing environment we currently find ourselves in has intensified beyond historical norms."*

Tim Crew, CEO of US generics player Lannett, perhaps summed up the current situation for generics players most succinctly, as the company reported financial second quarter results at the start of February that demonstrated the toll that had been taken on the firm's sales and profits by these pricing pressures. (Also see "*Lannett: Pricing Pressure Has 'Intensified Beyond Historical Norms'*" - Generics Bulletin, 7 Feb, 2022.)

"The competitive pricing environment we currently find ourselves in has intensified beyond historical norms and our recent expectations," Crew described, referring to this as an "industry-wide phenomenon."

"The pricing environment in the generic industry has been exceptionally competitive," he elaborated. "While there may be a number of reasons for the situation, we believe perhaps the primary cause is related to fewer approvals of newer generic products, particularly important to manufacturers and customers alike, and relatively higher number of approvals and related launches for older and already competitively priced oral generic products."

Lannett is far from the only company to have spoken out on how these pressures are limiting prospects for the generics industry. Leading player Sandoz also saw its business suffer in 2021 on the back of continued price erosion and an unfavorable product mix, "particularly in the US."

Overall, seven percentage points of volume growth for Sandoz last year was outweighed by a nine-point negative price impact, leading the firm's annual turnover to decline by 2% at constant currencies to $9.63bn. (Also see "*Sandoz Lays Out Plan For Rebound With Top Line Stagnant In 2021*" - Generics Bulletin, 4 Feb, 2022.)

Moreover, Sandoz has warned that in 2022 its core operating profit is expected to decline by "low to mid-single digits, mainly driven by growth margin pressures due to pricing and product mix."

Another leading player in the industry, Viatris, has also seen its profit forecasts shrink in recent months as a result of inflationary pressures. (Also see "*Viatris Aims To Clear Up Investor 'Disappointment' After Breaking EBITDA Baseline*" - Generics Bulletin, 10 Mar, 2022.)

And Teva also saw its sales suffer in 2021 – with the firm reporting North America generics sales down by 6% to $3.77bn – albeit citing multiple factors including the impact of COVID-19 on volumes as well as a recent lack of significant launches. (Also see "*Leaner Teva Bolsters Margins With 2022 Expected To Be Trough Year*" - Generics Bulletin, 11 Feb, 2022.)

Hikma Chief Sees Tough Conditions Ahead

Some of the most detailed commentary around the US pricing environment has come from Hikma. The company's CEO Siggi Olafsson warned earlier this year that pressures were continuing to intensify, following a "gradual worsening of the pricing environment" in 2021.

While US price erosion had been around 4% in 2020, Olafsson indicated, the full-year average for 2021 was closer to 8%, with levels rising to double-digits by the end of the year (*see sidebar*).

"In terms of how long this will last, you never know," Olafsson said. "But I believe – and I've been doing this now for just over 20 years – the pricing in the US is cyclical."

"You usually have at maximum two challenging years, and then you usually have three to four very decent years," he outlined.

"We had 2016 and 2017, which were challenging years for pricing; we had 2018, 2019 and 2020, quite good years; we had a change of the storm a little bit in 2021; and we are forecasting low-double-digit pricing [erosion] for 2022, based on the tenders that we see and the expectation in the market."

Hikma Warns Of Renewed Pricing Pressure On US Generics

By David Wallace

03 Mar 2022

Hikma has warned of renewed pressure on generics in the US after a "gradual worsening of the pricing environment" in 2021. However, the company still managed to achieve growth of a tenth in its generics segment last year, on the back of key launches.

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Olafsson pointed out however that Hikma's business was proving "resilient," adding that "looking at the top 15 companies in this space, Hikma was only one of four leading companies to achieve growth in 2021."

But "we are expecting a little bit worse a situation in 2022 than in 2021," he acknowledged in a recent interview with *Generics Bulletin*. "We are guiding towards very low double-digit numbers, about 10% maybe for 2022," he confirmed. But "I think that the company is well-prepared for it." (Also see "*Hikma Is Prepared For Tougher Pricing Environment In 2022*" - Generics Bulletin, 10 Mar, 2022.)

"My theory as always is that when you have a tough environment, you need to run the business for the bottom line," Olafsson explained. "I sometimes joke about it, that anyone can make a top line in generics, you just have to give discounts and then you can build a very beautiful top line. But you really need a strong team to build the bottom line…you need to make the right decisions and you need to think about your costs."

"I'm always optimistic," he concluded. "I think it's cyclical – I think 2021 and 2022 are a little bit compensating for the pandemic, where the focus was on the supply and not so much on pricing, but I think then in 2023 hopefully we have a little bit better situation."

Meanwhile, Amneal was another major US supplier that offered a touch of optimism alongside its acknowledgement of tough times to come. It expects to see mid-single digit growth for its generics business in 2022, accelerating from the 2% growth seen in 2021.

"Our growth will be led by retail generics as we introduce new products," the company forecasted, "and the strength of the recent launches enable us to offset low double digit price erosion, similar to what we saw in 2021." (Also see "*Amneal Delivers On Biosimilars Ambitions With Neupogen Rival*" - Generics Bulletin, 8 Mar, 2022.)

Indian Players Look To Launches To Offset US Downturn

Several leading Indian generics companies have also seen their US businesses hit by intensifying pricing pressures.

Alembic had last year warned that a change was coming in the US market, pointing to a challenging scenario due to price erosion, with this feeling particularly marked after a strong run for the firm over the past few years. (Also see "*US Price Erosion Dents Alembic*" - Generics Bulletin, 19 Nov, 2021.)

"We felt it more because the last three years have been quite phenomenal in terms of the pricing and the opportunities that we had in this [US] market," said managing director Pranav Amin. "As we move forward, we look forward to launching new products as well as picking up share in existing products."

For Glenmark, the expectation is that 6%-7% price erosion for the base business will continue in the US, with this mitigated by new launches such as injectables and nebulizers as well as its Ryaltris (olopatadine/mometasone furoate) nasal spray. (Also see "*Ryaltris US Debut Plan, Generic Spiriva Fuel Buoyant Glenmark Outlook*" - Generics Bulletin, 21 Feb, 2022.)

Similarly, Lupin is hoping that several impending high-value launches will put it back on track after seeing margins narrow in recent months. (Also see "*Looming Launches Predicted To Offset Lupin Pressures*" - Generics Bulletin, 18 Feb, 2022.)

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Meanwhile, Torrent saw one of the most severe impacts from US pricing pressures, with its results for its financial third quarter – the final quarter of calendar 2021 – reflecting a 20% drop in US revenues. The firm blamed this on price erosion in the base business following "higher than anticipated pricing pressure," as well as a lack of new approvals. However, it is also banking on future launches to steady the ship. (Also see "*Torrent Sees US Sales Decline By 20%*" - Generics Bulletin, 1 Feb, 2022.)

Buyer Consolidation Puts Market In Jeopardy

Suggesting that purchaser consolidation was one of the underlying factors responsible for the squeeze on generics suppliers, generics and biosimilars body the US Association for Accessible Medicines recently called on the US Federal Trade Commission and the antitrust division of the Department of Justice to address anticompetitive challenges in the generics industry that were rooted in this monopsony.

Buying groups have substantially consolidated buying power in the US generics market, with three major buying groups now responsible for 92% of generic drug purchases.

ClarusOne/McKesson accounts for 21% of the market, while CVS and Cardinal's Red Oak Sourcing makes 34% of generic drug purchases and Walgreens Boots Alliance makes 37% (*see sidebar*).

The AAM says this has led to unsustainable generic drug prices and margins on some products, which in turn has caused volatile supply and risks of drug shortages. It noted that, of the 65 generic drugs approved in 2020, only 25 were commercially available by December that year, owing to "lack of business viability."

AAM Calls Out Threat Of Consolidation Among Purchasers

By Chloe Kent

24 Mar 2022

Drug buying groups and pharmacy benefit managers are leaving generic drug producers unable to compete even when they have viable products due to concentration of buyer power, the Association for Accessible Medicines has highlighted.

Read the full article here

"Notwithstanding the economic principle that more suppliers of a good or service tend to create lower prices for consumers," commented AAM president and CEO Dan Leonard, "the imbalance between 200 generic competitors and a handful of purchasers is not sustainable – and indeed, has lessened competition in this very important space."

The AAM has also pointed to problems with the consolidation of pharmacy benefit managers, with just three PBMs controlling nearly 80% of the market. OptumRX controls 21% while Express Scripts controls 24% and CVS Health controls 32%.

PBMs are not required by federal law to disclose the rebates they receive from drug makers, or the difference between what they are paid by insurers to fill a prescription and how much they pay the pharmacy that fills it.

And according to the AAM, PBMs have "dramatically" expanded their formulary exclusion lists in recent years, allowing them to "extract sizable rebates from brand manufacturers for brand medicines on formulary, limiting generic manufactures' ability to gain market share when a generic launch occurs."

"Increased scrutiny is required in this sector, where the three largest PBMs and the four largest commercial health insurers account for more than 80% of their respective markets," the AAM insisted.

Meanwhile, markups by supply-chain middlemen are also distorting the generics market, the association believes, creating a "wide gulf" between what drug makers charge to the supply chain for their medications when they leave the factory and what patients can spend when paying cash to fill their prescription at a pharmacy. (Also see "*'Middlemen' Markups Are Penalizing Patients, Says AAM*" - Generics Bulletin, 14 Mar, 2022.)

'Urgent' Need To Stop Downward Price Pressures In Europe

While many of the headlines focusing on pricing pressures have concentrated on the US market, other territories are no stranger to similar pressures.

In Japan, pricing pressure has led to cost squeezes that have been blamed by some stakeholders for putting the supply chain at risk (Also see "*A Year's Struggle: How Japan Is Recovering Damaged Generic Supplies After Quality Violations*" - Scrip, 12 Apr, 2022.), while further Japanese price reductions for generics have been lined up by the country's Ministry of Health, Labour and Welfare just this month. (Also see "*What's Next? Five Things To Look Out For In April*" - Generics Bulletin, 1 Apr, 2022.)

And in Europe, pricing concerns have been raised by local industry association Medicines for Europe, with president Elisabeth Stampa warning that "driving prices down is certainly not helping to sustain our sector," especially against the backdrop of healthcare systems and supply chains that are still emerging from the COVID-19 pandemic.

"We are coping with increasing inflation and transportation costs at the same time, while governments are still focusing very much on austerity measures and the lowest possible price," Stampa explained (*see sidebar*).

Stampa Urges Investment In European Manufacturing

"There is definitely an urgency in stopping those downward pricing pressures," she maintained, "because they are only making the problem worse than it already is."

Meanwhile, attracting greater investment in European manufacturing – for both formulations and active pharmaceutical ingredients – would be made easier if procurement processes could be encouraged to move away from cost as the sole or deciding factor, she suggested.

By David Wallace

22 Mar 2022

Fresh from being named as the new president of Medicines for Europe, Medichem CEO Elisabeth Stampa sets out the association's priorities around investment in European manufacturing, as well as identifying key obstacles that must be overcome to create a sustainable environment for off-patent medicines, in an exclusive interview with *Generics Bulletin*.

Read the full article here

One example that has demonstrated the precarity of supply in Europe – and the way in which focusing on ever-lower prices can put access at risk – is the recent shortage in Germany of breast cancer drug tamoxifen, after certain suppliers exited the market because the product was no longer economical to supply. (Also see "*German Tamoxifen Shortage Shows Consequences Of Cost Containment*" - Generics Bulletin, 17 Feb, 2022.)

Medicines for Europe said the case exemplifies an "urgent need to revise unsustainable pricing and tendering policies," suggesting that it is "indicative of a growing trend of generic market policy failures, caused by disproportionate and short-sighted cost-containment measures combined with rapid increases in inflation."

> *"It's a matter of price, of not putting all the pressure on price."*

Asked about tamoxifen in Germany, Stampa was clear on how similar situations could be avoided in future.

"It's a matter of price, of not putting all the pressure on price," she summarized. "It's a matter of tenders with multiple winners [and] implementing the Most Economically Advantageous Tender (MEAT) system with other considerations than strictly price."

But asked whether the political will existed to shift away from the focus on price, she conceded that "it will be very difficult to move away. The population is only going to get older, which is only going to cost more money. And at the same time there are new fantastic therapies which have to be covered. So we need to find a way of moving forward with the healthcare systems that everyone wins."

Nevertheless, she said, tangible examples such as the German tamoxifen shortage "will help to change minds, because it is definitely creating awareness."

Q1 Results May Give Fresh Indication Of Pricing Landscape

As the generics industry prepares for the latest round of company financial results – with many firms reporting how they have fared in the first quarter of 2022, at the same time as others, particularly in India and Japan, provide overviews of their full financial years – it remains to be seen how these pricing pressures will develop overall, and how business outlooks will be affected.

However, based on the most recent evidence it seems as though any company with major interests in the US in particular will be looking to limit the damage of price erosion in their portfolio, while also banking on new approvals and launches to help to offset the effect of downwards price pressure on more established products.

And depending on how long this latest period of intensive pricing pressure persists and how severe the effects prove to be – at a time when costs are also rising rapidly across the board – more far-reaching changes could also be on the horizon, both within individual companies and for the generics landscape as a whole.

Ultimately, for the generics industry to be able to fulfil its full potential, it needs to be able to offer cost-effective alternatives to more expensive branded treatments – but not at pricing levels that are set so low as to make the entire off-patent framework unsustainable.