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Viatis Is 'Not Walking Away' From Generics

Amid Steep Q1 Drop In Complex Generics, Company Reaffirms Commitment

by David Wallace

After reporting sliding sales for both generics and complex generics in Q1, Viatis has nevertheless reaffirmed its commitment to the off-patent sector, highlighting in particular a planned launch this year of its Breyna rival to Symbicort.

Viatis is not turning its back on small-molecule oral solid generics or more complex generics, the company has insisted, as it faced questions over its long-term commitment to the generics sector during its first-quarter earnings call.

During the first quarter, the firm's complex generics sales slid by 65% as reported – and by 40% when adjusted to exclude its divested biosimilars from the formerly joint category (Also see "*Biocon Closes \$3bn Deal For Viatis Biosimilars*" - Generics Bulletin, 30 Nov, 2022.) – to \$136m. Viatis admitted that this was "lower than expectations", with the fall "primarily due to phasing of certain products."

Meanwhile, generics sales dropped by 6% as reported to \$1.16bn. The firm nevertheless said this was "ahead of expectations, including strong performance across broader developed & emerging markets portfolios." Along with branded sales down by 5% to \$2.42bn, total turnover fell 11% as reported and 6% operationally to \$3.72bn.

Against this backdrop – and shortly after the arrival of brand industry veteran Scott Smith as CEO (see sidebar) – management was asked how Viatis now considered the generics business as part of its overall operation, in particular whether solid-

Viatis To Bring In Plenty Of Brand Knowledge With New CEO Smith

dose generics would see a decline in emphasis over time.

Viatis president Rajiv Malik was clear that “we’re not walking away from that segment.” He also countered suggestions that the firm was “de-emphasizing the [generic] oral product business” and suggesting instead that portfolio changes were more a rationalization in the face of increased competition on certain products.

By [Dean Rudge](#)

27 Feb 2023

Only three months after joining Viatis’ board of directors, Scott Smith, famed for spearheading Celgene’s successful and lucrative Inflammation and Immunology division, has been announced as the company’s new CEO, beginning 1 April.

[Read the full article here](#)

“We diligently looked into our portfolio,” he explained, finding that many products were “commoditized – there are more than 10, 15 suppliers out there. Access is not an issue.” So “we pruned that portfolio and focused on going up the value chain,” concentrating instead on more complex and harder-to-make products.

“So I would say that generics are still a very important part,” Malik summarized. “Basically, it’s all about access, and that’s where we have been focusing – on bringing access to hard to make, difficult products in this segment across the globe.”

Restasis Exclusivity Last Year Offers Unfavorable Q1 Comparison

Meanwhile, addressing the Q1 results, Malik acknowledged that the base business erosion had come from complex generics, largely driven by North America.

“One was Restasis because we had almost exclusivity last year over this period,” Malik said, referring to its introduction of the first generic version of the cyclosporine 0.05% ophthalmic emulsion. (Also see “[Surprise! Viatis Proves Its Worth With First Generic Restasis Approval](#)” - Generics Bulletin, 3 Feb, 2022.) Apotex had a US generic approved at the start of this year.

And on the firm’s Wixela Inhub (fluticasone/salmeterol) rival to Advair, “we are seeing some hyper competition,” he suggested, with Hikma and Teva also now having generic versions in the market. Hikma recently registered an impairment in connection with its own expectations for its generic. (Also see “[Hikma Manages To Stay Flat In 2022 Despite Generics Pressures](#)” - Generics Bulletin, 1 Mar, 2023.)

Along with additional competition on Xulane (ethinylestradiol/norelgestromin) from Amneal, Malik said “I think the three products largely contributed to the erosion in the North America in the complex generics category.”

“But as we look forward, I think we’re looking forward to, in fact, bringing the developed markets back to growth in the second half of the year.”

Launch Of Breyna Rival To Symbicort Is On The Horizon

One product highlighted as a particular growth opportunity was the Breyna rival to AstraZeneca’s Symbicort (budesonide/formoterol fumarate dihydrate) for which Viatris won US approval more than a year ago. (Also see "[Viатris Wins First US Symbicort Generic – Will It Launch At Risk?](#)" - Generics Bulletin, 16 Mar, 2022.)

After extended legal wranglings over the respiratory product (Also see "[As US Court Chops Another Symbicort Patent, Will Viатris Make Its Move?](#)" - Generics Bulletin, 11 Nov, 2022.), Viatris and partner Kindeva Drug Delivery recently settled litigation with AstraZeneca and “expect to launch the product after expiration of regulatory exclusivity,” Malik indicated, with a North American launch planned for this year.

“We anticipate launching Breyna with 180 days first-to-file generic exclusivity,” he added, “subject to FDA’s future determination of the issue, if and when another ANDA filer becomes eligible for final approval.”

Asked during the results call whether the Symbicort rival may end up facing similar competitive pressures to Wixela Inhub, Malik maintained that “Wixela is and Wixela always has been ever since launch, a very meaningful contributor – even this quarter it has been a very decent contributor.”

“It’s a very important product. We have met and exceeded every expectation we had around Wixela.” And Viatris would expect to “leverage what have we learned in the market” to the benefit of Breyna, he indicated.

Viатris was “very much looking forward” to launching Breyna, Malik reiterated, underlining that “once the regulatory exclusivity expires, everything is lined up.”

And looking a little further ahead, Viатris also confirmed that it had filed its monthly glatiramer acetate product with the FDA, with launch expected in 2024. (Also see "[Viатris’ Once-Monthly Copaxone Filing Imminent, Botox ‘On Track’](#)" - Generics Bulletin, 23 Jan, 2023.)