GENERICS BULLETIN

25 Mar 2024 | News

Meitheal Prepares For Major US Injectables Push

Plans To Launch 'Up To 20 New Products' In 2024 Following Bupivacaine Introduction

by David Wallace

Meitheal Pharmaceuticals says it is preparing to launch "up to 20 new products" this year in the US following a recent expansion of its generic injectables portfolio.

Meitheal Pharmaceuticals says a recent deal to expand its generic injectables portfolio will allow the firm to launch "up to 20 new products" this year in the US "to support a sustainable US drug supply." The firm intends to build on its recent launch of multiple presentations of bupivacaine hydrochloride injection to supply further products that have recently experienced shortages.

In October 2023, Meitheal announced that it had expanded its generic injectables portfolio through an asset purchase agreement for a "broad portfolio of generic injectables" by parent company, Hong Kong King-Friend Industry Co., known as HKF. The agreement increased Meitheal's total generic injectables portfolio to 82 products.

Tom Shea, CEO of Meitheal, called the deal a "significant milestone" for the firm's portfolio that "reinforces our commitment to simplifying access to life-changing medicines through global partnerships."

Under the agreement, HKF will acquire "the right, title and interest, to 18 additional generic injectable products within the US," with HKF responsible for development and manufacturing and Meitheal gaining exclusive US commercialization rights.

And now, Meitheal says it is "preparing to launch up to 20 new products in 2024 to support a sustainable US drug supply," building on its recent launch of bupivacaine.

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"Meitheal is pleased to further expand our portfolio of sustainably manufactured and priced generic injectables as we bring additional presentations of bupivacaine hydrochloride injection to market during this time of product shortage," said Shea. "As we prepare to launch multiple new products in 2024, we are intently focused on expediting delivery of medicines in short supply."

"With over \$100m invested in generic R&D over the past six years," Shea underlined, "Meitheal is fully committed to pursuing efficient drug development and commercialization to simplify access to life-changing medicines for all patients." (Also see "Meitheal Reveals Manufacturing Expansion Plans" - Generics Bulletin, 13 Feb, 2020.)

A capital investment of over \$100m by Meitheal's parent company Nanjing King Friend Biochemical Pharmaceutical (*see sidebar*), saw the completion of "a brand new, state-of-the-art manufacturing workshop" in 2023.

This was inspected by the US Food and Drug Administration in November of 2023, resulting in the approval of five new lines.

"These approved lines add over 200 million units of capacity for vial and cartridge products that support current and future demand for generic

China's Nanjing King-Friend Takes Control Of US Injectables Specialist Meitheal

By David Wallace

12 Aug 2019

China's Nanjing King-Friend Biochemical Pharmaceutical has taken a majority stake in US generic injectables specialist Meitheal Pharmaceuticals.

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injectables," Meitheal noted. "These lines are expected to produce commercial products that will have an impact on drug shortages beginning in the second half of 2024."

"Meitheal is planning for the launch of multiple new products in 2024 across its core therapeutic areas of anti-infectives, anesthetics, critical care, fertility, and oncology by continuously evaluating new product opportunities and prioritizing those that address gaps in the current marketplace."

As well as generic injectables, Meitheal is also active in biosimilars. The firm last year obtained rights to insulin aspart, insulin lispro, and insulin glargine, via Nanjing King-Friend. (Also see "Meitheal Looks To Chinese Parent To Bring In Three US Insulin Biosimilars" - Generics Bulletin, 10 Oct, 2023.) And towards the end of the year, the firm announced that it was joining the US Biosimilars Forum industry association. (Also see "Amneal And Meitheal Join Biosimilars Forum" - Generics Bulletin, 19 Oct, 2023.)