

April 12, 2023

To: The Office of Attorney General of Vermont

Via Email: AGO.highcostprescriptiondrugs@vermont.gov

Re: Meitheal Pharmaceuticals, Inc. New Drug Report – Generic Mitomycin for Injection, USP 40mg.

To whom it may concern:

On March 15, 2023, and in accordance with the requirements set forth in the 18 V.S.A. § 4637 (b), Meitheal Pharmaceuticals, Inc. submitted a New Drug Notice on generic Mitomycin for Injection, USP 40mg.

Product Name and Description	NDC Number	WAC Price	Effective Date
Mitomycin for Injection, USP 40mg 100mL SDV	71288013951	\$1,263.96	3/14/2023

Meitheal Pharmaceuticals, Inc. now provides the following additional information pursuant to 18 V.S.A. § 4637 (c):

Marketing and Pricing Plans Used in Launch: Meitheal markets generic Mitomycin for Injection 40mg as a therapeutic equivalent to the innovator (brand) drug in the U.S. As such, Meitheal relies on the safety and efficacy findings of the FDA with respect to the innovator drug. Meitheal primarily markets to group purchasing organizations (GPOs), Integrated Delivery Networks (IDNs), and hospital/alternate site (own use) customers based solely on price and availability and therefore does not engage in direct-to-consumer, direct-to-physician, or prescriber marketing. Meitheal does not market based on any aspects of the drug itself, nor does Meitheal aim to treat a certain number of patients. Rather, Meitheal evaluates the size of the total market for a particular drug and strives to achieve a certain market share for that product. The target users of Mitomycin for Injection are large cancer centers, teaching hospitals and cancer clinics.

Mitomycin for Injection 40mg is used primarily for the treatment of cancer of the stomach or pancreas that has spread to other parts of the body and has not improved or worsened after treatment with other medications, surgery, or radiation therapy.

Estimated Volume of Patients: Meitheal's best estimate regarding patient population is approximately 90,550 patients on an annual basis. This is based on cancer.org which states the patient population of 90,550 of stomach or pancreas cancer patients on a annual basis.

Breakthrough Therapy Designation or Priority Review: Neither. The product was not granted priority review and did not receive a breakthrough therapy designation from the FDA.

Date and Price of Acquisition: Not applicable. This product was not the result of an acquisition.

Thank you for your consideration.

Sincerely,

Karen Nieves
Contract Coordinator
Meitheal Pharmaceuticals, Inc.