

February 8, 2024

To: The Office of Attorney General of Vermont

Re: Meitheal Pharmaceuticals, Inc. New Drug Report – Generic Thiotepa for Injection, USP 100mg.

To whom it may concern:

On January 9, 2024, 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 Thiotepa for Injection, USP 100mg.

Product Name and Description	NDC Number	WAC Price	Effective Date
Thiotepa for Injection, USP 100mg 10mL SDV	71288015710	\$2,350.00	1/9/2024

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 Thiotepa for Injection USP 100mg/vial, as a therapeutic equivalent to Adienne SA's NDA#208264 Tepadina for Injection 100mg/vial (marketed by Amneal). As such, Meitheal relies on the safety and efficacy findings of the FDA with respect to the reference listed drug. Meitheal 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 it 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.

Thiotepa for Injection is a drug used to treat certain types of bladder cancer, breast cancer, ovarian cancer, and malignant effusion (a condition in which cancer causes an abnormal amount of fluid to collect in hollow spaces or between tissues of the body). The total number of cases for these types of cancer in the US is 495,150 cases per year according to the National Cancer Institute.

Estimated Volume of Patients: The total number of cases for these types of cancer in the US is 495,150 cases per year or on average 41,262 cases per month.

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.

Sincerely,

Karen Nieves

Karen Nieves | Contract Coordinator

Meitheal Pharmaceuticals, Inc.

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