

Shilpa Medicare Limited

Corporate & Admin Office:

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CIN: L85110KA1987PLC008739

23 May 2023

Corporate Relationship Department,
BSE Limited
Phiroze Jeejeebhoy Towers,
Dalal Street, Fort,
Mumbai-400 001

National Stock Exchange of India Limited
Exchange Plaza, 5th Floor,
Plot No.C/1, G Block
Bandra Kurla Complex, Bandra (E)
Mumbai-400 051

Dear Sir/Madam,

**Sub: Intimation U/R 30 of the SEBI(LODR) Regulations- Reg.
Ref: Stock Code: NSE: SHILPAMED/BSE-530549**

Shilpa Medicare’s New Drug Application for Pemetrexed Injection 1000 mg/100 ml, 500 mg/50 ml & 100 mg/10 ml, Ready to Use formulation is approved by US FDA

This is to inform you that **Shilpa Medicare’s New Drug Application for Pemetrexed Injection 1000 mg/100 ml, 500 mg/50 ml & 100 mg/10 ml, Ready to Use formulation is approved by US FDA.**

This is the first NDA product approval received by the Company under 505(b)(2) application, which is a unique formulation supplied as ready to use product solution. This product is required to be administered intravenously without any further dilution. The product is stable at room temperature.

The company has developed Pemetrexed formulation as liquid/ ready to use injection against Lyophilized powder formulation of reference ALIMTA®. The product approval has been received for the application filed from a third party manufacturing site. The Company has already entered into a commercialization agreement with Amneal Pharmaceuticals LLC for the US Market.

Pemetrexed injection is used in the treatment of Non-small cell lung cancer & Malignant pleural mesothelioma as approved in the Prescribing Information.

According to IQVIA MAT Q1 2023 data, the US market for **Pemetrexed Injection** is approximately USD 735.3 Million.

With Regards,
For **SHILPA MEDICARE LIMITED**

Ritu Tiwary
Company Secretary & Compliance Officer