



## **Shilpa Medicare Limited**

### **Corporate & Admin Office:**

"Shilpa House", # 12-6-214/A-1, Hyderabad Road,  
Raichur – 584 135, Karnataka, India  
Tel: +91-8532-238704, Fax: +91-8532-238876  
Email: info@vbshilpa.com, Web: www.vbshilpa.com  
CIN: L85110KA1987PLC008739

**Date: 22<sup>nd</sup> September, 2025**

To,

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

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

**Ref: Stock Code: NSE: SHILPAMED/BSE-530549**

Dear Sir/Madam,

**Sub: Intimation U/R 30 of the SEBI(LODR) Regulations- Reg.**

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### **Initial Authorization for Rivaroxaban Orodispersible Films from Europe**

This is to inform you that Shilpa Medicare Limited, headquartered at Raichur, Karnataka, India, has received the Initial Authorization from European Medicine Agency (EMA), recommending the grant of the final Marketing Authorization for Shilpa Medicare's medicinal product, **Rivaroxaban 10 mg, 15 mg, and 20 mg Orodispersible Films**.

This application, submitted as a hybrid application via the EMA's Centralized Procedure, is a generic version of the innovator product Xarelto®, from Bayer AG, which is available as oral tablets. Shilpa's product is bioequivalent to the reference product Xarelto® and is the only Rivaroxaban in ODF form which can help in patient comfort, especially in geriatric patients.

Shilpa's Rivaroxaban Orodispersible Films is an anticoagulant medicine (a medicine that prevents blood clotting). It is used to treat deep vein thrombosis and pulmonary embolism, and to prevent their recurrence in adults. It is also used to prevent atherothrombotic events (such as heart attack, stroke or death from heart disease) in adults. It works by inhibiting a highly selective, direct factor Xa.

The total Europe market for oral Rivaroxaban formulations is about USD 2.5 billion.

This approval has come from the Company's finished dosage form manufacturing facility, Shilpa Medicare Ltd, Unit VI, located at Dabaspeth, Bengaluru, Karnataka. The facility is currently approved by USFDA, Europe and MHRA UK. This is the third approval of a prescription oral mouth dissolving film product in the European markets from this facility. The facility is involved in manufacturing, packaging, labelling and testing of specialized finished dosage forms as oral dispersible/dissolving Films and Transdermal Patches.

This is for your information and records.

**For SHILPA MEDICARE LIMITED**

**Ritu Tiwary**  
**Company Secretary & Compliance Officer**