

MAYNE PHARMA ANNOUNCES APPROVAL OF ADDITIONAL KAPANOL® DOSAGES IN SWITZERLAND

03 June 2024, Adelaide Australia: Mayne Pharma Group Limited (ASX: MYX) is pleased to announce that Swissmedic, the national authorisation and supervisory authority for drugs and medical products, has approved KAPANOL® (morphine sulfate pentahydrate) 10 mg and 200 mg capsules for the treatment of moderate to severe prolonged pain and opioid substitution treatment (OST) in Switzerland¹.

Lipomed AG has an exclusive license from Mayne Pharma to register, distribute and sell KAPANOL® in Switzerland and other EU territories. Other strengths of KAPANOL® (20 mg, 50 mg and 100 mg) were approved by Swissmedic for the treatment of OST in October 2021, in addition to the previously approved indication for the treatment of moderate to severe chronic pain.

KAPANOL® capsules contain polymer-coated pellets which provide sustained-release of morphine sulfate after they are swallowed. This formulation is designed for once-a-day administration with reduced fluctuation in plasma morphine levels, making it suitable for use in OST.^{2,3} The approval of the 200 mg strength decreases the pill burden for patients undergoing OST with higher doses.

According to IQVIA, a leading healthcare data and analytics provider, the market in Switzerland for sustained release oral morphine used in OST is US\$11.0 million.⁴

KAPANOL® was developed by Mayne Pharma and is manufactured at its site in Salisbury, South Australia and distributed in several countries around the world including Canada, Switzerland and Thailand.

Mayne Pharma is working to expand capacity and capability through the installation of new equipment including a high-speed encapsulator and high-speed blister packing line, with integrated end-of-line serialisation equipment to support international markets. This project is supported by \$4.8 million of funding from the Federal Government Modern Manufacturing Initiative (MMI) Grant program.

In Australia, KAPANOL® 10mg, 20mg, 50mg and 100mg capsules are indicated only for the relief of chronic pain unresponsive to non-narcotic analgesia and for the treatment of chronic breathlessness in palliative care patients with advanced disease (10mg and 20mg only).

Mayne Pharma's CEO, Mr Shawn Patrick O'Brien said "Mayne Pharma is pleased about the approval of these additional dosages of KAPANOL® in Switzerland and believe they can help physicians manage the challenges of OST and enhance patient care. This program is an example of the Company's commitment to supporting therapeutic areas of need outside of the US and Australia."

¹ Swissmedic has approved KAPANOL® prolonged-release capsules for: (a) the treatment of moderate to severe prolonged pain or in cases of insufficient efficacy of non-opioid analgesics and/or weak opioid analgesics; and (b) oral substitution treatment of opioid dependence in the context of a medical, social and psychological therapy.

² Broomhead, Alan, et al. "Comparative single-dose pharmacokinetics of sustained-release and modified-release morphine sulfate capsules under fed and fasting conditions." *Clinical drug investigation* 13 (1997): 162-170.

³ KAPANOL® (morphine sulfate pentahydrate) approved Product Information, dated 2 November 2023.

⁴ IQVIA data MAT July 2023.



ASX Announcement

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Authorised for release to the ASX by the Chair

KAPANOL® is a registered trade mark of Mayne Pharma International Pty Ltd.

About Mayne Pharma

Mayne Pharma is an ASX-listed specialty pharmaceutical company focused on commercialising novel pharmaceuticals to offer patients better, safe and more accessible medicines. Mayne Pharma also provides contract development and manufacturing services to clients worldwide. Mayne Pharma has a 40year track record of innovation and success in developing new oral drug delivery systems. These technologies have been successfully commercialised in numerous products that continue to be marketed around the world. To learn more about Mayne Pharma, please visit maynepharma.com.

About KAPANOL®

In Australia, KAPANOL® contains the active ingredient morphine sulfate pentahydrate. KAPANOL® 10 mg, 20 mg, 50mg and 100 mg capsules are used for the relief of severe pain which is opioid-responsive. KAPANOL® 10 mg and 20 mg capsules are also used for the relief of distressing chronic breathlessness in the palliative care of patients with severe chronic obstructive pulmonary disease (COPD), cardiac failure, malignancy or other causes. For more information, see the full Consumer Medicine Information, available [here](#).