

6 December 2019

# **ASX ANNOUNCEMENT**

# Penthrox Marketing Authorisation Application in Russia

Medical Developments International Limited (ASX: MVP) announced today that the Russian Ministry of Health has accepted MVP's Marketing Authorisation Application (MAA) for review. MVP submitted the MAA for Penthrox on 30 September and after a two-month validation period, the Russian Ministry of Health advised that the Penthrox MAA had been accepted.

At this stage MVP has been advised that no further clinical work is required in Russia and that the Ministry of Health intend to review the same "Clinical, Safety and Efficacy" data, which MVP used to support the approval of Penthrox in Europe and elsewhere.

MVP's application to the Ministry of Health is for Penthrox to be approved for Trauma Pain.

The Penthrox MAA was submitted under the new unified Eurasian Economic Union (EAEU) rules. The EAEU rules means MVP's application is for Penthrox to be approved for sale in Russia, Belarus, Kazakhstan, Armenia and Kyrgyzstan. The review process and final approval in Russia is expected within 15 months and the remaining countries are expected within 2 years.

The acceptance of the MAA triggers a milestone payment from our Russian partner.

Chief Executive Officer of MVP, Mr. John Sharman, said: "We have been working on our MAA in Russia for several years and its acceptance for review by the Ministry of Health is a significant achievement and pointer to our future in Europe."

Lancet's CEO, Mr. Anton Zybin said: "Lancet, is one of Russia's biggest and fastest growing pharmaceutical companies. The Russian market has an unmet commercial need for a strong non-opioid analgesic like Penthrox and the ultimate approval by the Russian Ministry of Health of Penthrox will be very positive for MVP and Lancet."

Authorised for release by MVP Chairman, David Williams.

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#### **About Penthrox®**

Penthrox is a fast onset, non-opioid analgesic indicated for pain relief by self-administration in patients with trauma and those requiring analgesia for surgical procedures. Penthrox is now approved for sale in more than 40 countries and has been used safely and effectively for more than 40 years in Australia with more than 7.0 million units sold. There is growing interest in Penthrox being used in patients undergoing investigatory procedures, as well as operational procedures such as colonoscopy.

### **About Medical Developments International Ltd**

MVP is an Australian company delivering emergency medical solutions dedicated to improving patient outcomes. MVP is a leader in emergency pain relief and respiratory products. The Company manufactures Penthrox®, a fast-acting trauma & emergency pain relief product. It is used in Australian Hospitals including Emergency Departments, Australian Ambulance Services, the Australian Defence Forces, Sports Medicine and for analgesia during short surgical procedures such as Dental and Cosmetic surgery as well as in other medical applications. MVP is expanding internationally and manufactures a range of world-leading Asthma respiratory devices.

## **About JSC Lancet**

JSC Lancet supplies pharmaceuticals and healthcare equipment to Russian hospitals and healthcare centres. Lancet is one of the fastest growing pharmaceutical companies in Russia. The company's partners include Novartis, GSK, Pfizer, Bayer, AstraZeneca, Teva, Roche and others.