

6 May 2015

## ASX Announcement

# Penthrox successfully completes its Decentralised Regulatory Approval Procedure in Europe

Medical Developments International Limited (ASX: MVP) is delighted to announce that the Medicine and Healthcare products Regulatory Agency (“MHRA”) has issued the Final Assessment Report with the support of France, Belgium and Ireland authorities noting all outstanding issues pursuant to the Decentralised Procedure have been successfully resolved and Penthrox is approvable.

MVP now moves into the National Phase which is a purely administrative process whereby each of the countries approve the translation of the labelling and product information, and registers Penthrox as being available for sale in their national records. The National Phase should take 30 days and thereafter Marketing Authorisation will be issued and Penthrox will be available for sale in these markets.

MVP already has Galen Limited as its Licensing and Distribution Partner in the UK and Ireland and expects sales to commence within the next three months. Upon approval MVP will receive a second milestone payment of circa \$850,000 dollars, with additional sales based milestone payments to follow.

MVP CEO, Mr. John Sharman said, “The initial approval of Penthrox for use in the United Kingdom, France, Belgium and Ireland is the most significant event in the company’s history. In these four countries there are more than 50 million Accident & Emergency hospital attendances each year and we estimate these markets for Penthrox to be worth circa \$100 million per annum.”

Mr. Sharman said, “Penthrox is a category leading drug and we expect it can dominate many of the trauma and minor surgical procedure markets around the world. Penthrox has a number of very significant competitive and clinical advantages over its competitor products and we believe the market for trauma pain in Europe for an inhaled, fast acting, non-narcotic analgesic like Penthrox is very large.”

MVP Chairman, Mr. David Williams noted, “It will be fantastic to see Australia’s first choice, front line analgesic being used by foreign doctors, hospitals and ambulance. Our drug helps trauma patients relieve their pain quickly and also makes minor surgical procedures more comfortable. We are now well on our way in terms of delivering our globalization strategy for Penthrox.”

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### **About Pentrox**

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 has been used safely and effectively for more than 30 years in Australia with excess of 5.0 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.