

12 December 2017

ASX Announcement

Penthrox approved in another 22 European countries

Medical Developments International Limited (ASX: MVP) is delighted to announce that Penthrox has been approved for use in an additional 22 European countries today, further underwriting the confidence that global health authorities have in our dossier.

The Medicine and Healthcare products Regulatory Agency (“MHRA”) issued the Final Assessment Report with the support of all European country authorities noting the Decentralised Procedure (DCP) has been successfully completed. All countries have had the opportunity to review the dossier and in principal agree on the benefits of Penthrox as a widely used analgesic throughout Europe.

The successful DCP outcome approves the use of Penthrox in Austria, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Germany, Iceland, Italy, Latvia, Lithuania, Luxembourg, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden. Penthrox is already approved for use in the UK, Ireland, Belgium and France.

MVP now moves into the National Phase which is the administrative process whereby each country approves the translation of the labelling and product information, and registers Penthrox as being available for sale in their national records. At the completion of the National Phase, Marketing Authorisation will be issued and Penthrox will be available for sale in these markets. Each country’s Marketing Authorisation approval will be issued separately and MVP expect these 22 approvals to commence from January 2018.

MVP CEO, Mr. John Sharman said, “The approval of Penthrox for use in Europe is the single biggest achievement in the company’s history. This is a milestone for patients and physicians too: Penthrox can deliver outstanding value against the huge unmet need for fast, easy pain relief for patients who have experienced a trauma injury. By ensuring that a patient’s pain is quickly managed, Penthrox allows healthcare providers to treat the trauma injury faster. This ultimately simplifies the patient journey, helping address the suffering patients experience every day due to under-treatment and inadequate options for short term relief of moderate and severe trauma pain.”

Mr. Sharman said, “It will be a proud moment to see Australia’s first choice, front line analgesic being used by doctors, hospitals and ambulances throughout Europe. There are no other drugs like Penthrox. We are seeing the opportunities for Penthrox to treat patients with moderate to severe pain without the need to use dangerous opioids expanding globally and rapidly.”

Christian Mazzi, Chief Commercial Officer at Mundipharma International commented, “This Marketing Authorisation is a major step towards bringing Penthrox to people throughout Europe. We’re delighted to be able to continue our proud heritage as leaders in pain management and bring this important new, non-opioid based therapeutic to patients. We look forward to working with the different reimbursement bodies to make sure patients and hospitals have access to Penthrox as soon as possible.”



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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 40 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.

About the Mundipharma network

The Mundipharma global network of privately-owned independent associated companies was founded in 1956 by doctors, and now operates in over 120 countries worldwide. We are focused on developing business partnerships to identify and accelerate meaningful technology across an increasingly diverse portfolio of therapy areas including respiratory, oncology, pain, and biosimilars. Consistent with our entrepreneurial heritage, we like to think we see what others don't by challenging conventional wisdom and asking different and challenging questions. By working in partnership with all our stakeholders, the Mundipharma network develops medicines that create value for patients, payers and wider healthcare systems. For more information please visit: www.mundipharma.com.