



29 November 2016

## ASX ANNOUNCEMENT

# PENTHROX SUBMITTED FOR REGULATORY APPROVAL IN 22 EUROPEAN COUNTRIES

Medical Developments International Limited (ASX:MVP) is delighted to confirm that its partner in Western Europe, Mundipharma International Corporation Limited (Mundipharma) submitted an application on 28 November 2016 to the United Kingdom's Medicines & Healthcare products Regulatory Agency (MHRA) under the Decentralised Procedure to have Pentrox approved for sale in:

Austria	Bulgaria	Croatia	Cyprus	Czech Republic
Denmark	Estonia	Finland	Germany	Iceland
Italy	Latvia	Lithuania	Luxembourg	Norway
Poland	Portugal	Romania	Slovakia	Slovenia
Spain	Sweden			

The MHRA will again be the Reference Member State and will lead, manage and evaluate the regulatory application on behalf of the 22 countries listed. During the Decentralised Procedure each country will have an opportunity to ask questions, make comment and seek clarification. Once the MHRA has successfully closed out (approved) the Decentralised Procedure (210 days) each individual country then begins the National Phase, which is largely an administrative phase dealing with translations and packaging (30 days).

Following MDI's recent success in the UK, France, Belgium and Ireland via the Decentralised Procedure, the granting of each of the listed 22 countries Marketing Authorisation is expected throughout FY18.

The proposed indication is for the "Emergency Relief of moderate to severe pain in conscious adult patients with trauma and associated pain".

Sales from the countries listed above are expected to commence during FY18.

MVP CEO Mr. John Sharman said: "The submission of the 2<sup>nd</sup> DCP to have Pentrox approved for sale throughout the remainder of Europe is one of MVP's largest achievements to date. The regulatory process being undertaken is identical to our successful registration of Pentrox in the



UK, France, Belgium and Ireland. We expect Mundipharma to achieve regulatory approvals during FY18.”

In addition, national regulatory applications are expected to be filed with the relevant agencies within the Netherlands, Greece, Macedonia, Serbia, Albania, Liechtenstein, Montenegro, Kosovo, San Marino, Vatican City, Bosnia and Herzegovina, Andorra and Monaco in due course.

Mr Sharman said; “We are excited by the opportunity to sell Pentrox into the remainder of Europe. We have already delivered substantial orders into the French, UK, Irish and Belgium markets and this is a significant step forward in the globalisation of Pentrox.”

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### **About Pentrox**

'Pentrox' 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. 'Pentrox' 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 'Pentrox' 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 Pentrox<sup>®</sup>, a fast acting minor 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 Mundipharma**

The Mundipharma network of independent associated companies consists of privately owned companies and joint ventures covering the world's pharmaceutical markets. These companies are committed to bringing to patients the benefits of pioneering treatment options in the core therapy areas of pain management, oncology, respiratory and inflammatory conditions. Through innovation, design and acquisition, the Mundipharma network of independent associated companies delivers important treatments to meet the most pressing needs of patients, healthcare professionals and health systems worldwide.