

19 January 2015

ASX ANNOUNCEMENT

Green Whistle: Positive “Regulatory Approval” feedback from European Regulatory Authorities

Medical Developments International Limited (ASX:MVP) is delighted to announce that it has received positive feedback from the Medicine and Healthcare products Regulatory Agency (“MHRA”) to market and sell its inhaled analgesic product, ‘Penthrox®’ in the United Kingdom, and by extension to France, Belgium and Ireland via the Decentralised Procedure.

The MHRA has also outlined the timeframe for formal approval of Penthrox in these markets, which is expected to be completed within 90 days.

The MHRA states that based on its review of the data on quality, safety and efficacy of Penthrox, it *‘considers that the application for Penthrox in the treatment of pain relief by self-administration to conscious patients with trauma and associated pain is approvable provided that some listed outstanding points are satisfactorily addressed’*.

The outstanding points are a combination of labelling, training, administrative, quality, clinical and non-clinical matters which are already being addressed. MVP is confident it can address all the points in the coming weeks.

As a result of the pending Regulatory Approval, we estimate Galen Pharmaceuticals Ltd., MVP’s partner in the United Kingdom, may have the opportunity to sell ‘Penthrox’ into markets in the United Kingdom and Ireland in about April or May 2015. Plans for the Penthrox launch in these markets are already well underway.

MVP CEO, Mr. Sharman said, “The approval of Penthrox for use in the United Kingdom, France, Belgium and Ireland will be a company-making achievement for us. It opens up these European markets to Penthrox for the first time and more importantly, pursuant to the “Mutual Recognition” process for further regulatory approvals for other countries within the European Union.”

MVP Chairman, Mr. David Williams noted, “We are very proud of our achievements so far in Europe. Penthrox is a remarkable drug and it will be fantastic to see Australia’s first choice, front line analgesic used by foreign doctors, hospitals and ambulance. Our drug helps trauma patients relieve their pain quickly and also makes minor surgical procedures more comfortable.

This pending regulatory approval in in the United Kingdom, France, Belgium and Ireland is the first step in our globalization strategy for Pentrox, which is well underway.”

Mr. Sharman said, “The “Regulatory Dossier” used for the European Marketing Authorisation Application has been submitted to other regulatory agencies around the world with the purpose of getting Pentrox approved for sale in other markets. Included in the Regulatory Dossier is a range of clinical studies which have been conducted in the United Kingdom, Australia and elsewhere and which evidence and support the clinical efficacy and safety of Pentrox.

Mr. Sharman said, “We are in discussion with a number of business partners in various countries in Europe and elsewhere and we are hopeful we can agree terms and conclude negotiations in the coming months. Approval in Europe will facilitate ongoing partnership and licensing discussions and we are confident it will directly assist in obtaining regulatory approvals in other countries around the world.”

Enquiries:

David Williams
Chairman
Medical Developments International Ltd
0414383593

John Sharman
Chief Executive Officer
Medical Developments International Ltd
03 9547 1888



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 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.