Medical Developments International

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ASX ANNOUNCEMENT

Near term planning for the globalisation of Penthrox

The approval of Penthrox for use in the United Kingdom, France, Belgium and Ireland validates our Regulatory Dossier and the clinical and safety data we have obtained for Penthrox. It proves Penthrox is a "world class" product which regulatory authorities around the world can approve for sale.

With the successful closure of the Decentralised Procedure (DP) and ultimate approval in Europe, MVP plans to aggressively expand the number of countries which can sell Penthrox:

- In Europe, MVP will use its existing Regulatory Dossier and DP approval to apply via the Mutual Recognition Process (MRP) to other European Union countries to approve Penthrox for sale. The MRP usually takes circa 7 months. Our next wave of approvals will focus on the largest markets in Europe including Germany, Italy and Spain.
- Elsewhere in the world, our Regulatory Dossier which was used successfully in the United Kingdom, France, Belgium and Ireland has already been submitted or is in the process of being submitted to regulatory agencies in Russia, Saudi Arabia, Israel, Singapore, Hong Kong, Malaysia, Mexico, Taiwan and Iran. We expect regulatory approvals to sell Penthrox in these markets to be granted over the course of the next 12 months.
- In the USA we are focused on getting Penthrox approved for sale as soon as possible. Our initial advice is that our Regulatory Dossier can be used as the basis for our submission to the FDA, but we may need to complete another Phase III Clinical Trial to cover amongst other things, the FDA's ethnic patient enrolment requirements (e.g. Hispanic Americans, Asian Americans, African Americans,……). We are in the process of confirming our regulatory strategy with the FDA and will provide an update as to the expected approval timelines in due course.

Enquiries:

David Williams
Chairman
+61 (0) 414 383 593

John Sharman
Chief Executive Officer
+61 (3) 9547 1888

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 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.