Medical Developments International

29 August 2018

ASX Announcement

Penthrox: USA update

Medical Developments International Limited (ASX: MVP) advise that it has received correspondence from the USA Food & Drug Administration ("FDA") in relation to its Investigative New Drug ("IND") application to have Penthrox approved for sale in the United States of America.

The following is a broad summary of the additional information the FDA has requested:

- The FDA require MVP to identify an appropriate patient population for its suggested Phase I Study for whom the risk/benefit of Penthrox would be reasonable.

  In MVP's IND application, MVP suggested that the appropriate population would be Healthy Volunteers excluding patients who had previously developed hepatoxicity after administration of either methoxyflurane or halothane. The FDA has advised that it does not consider this population exclusion to be adequate. MVP believes it can identify an appropriate patient population and satisfy the FDA's concern.

- The FDA requested additional information and justification for the rare occurrence of idiosyncratic hepatoxicity.

  MVP believes it will be able to illustrate satisfactorily to the FDA the rare occurrence of idiosyncratic hepatoxicity and the acceptability of this risk in terms of the overall benefit of Penthrox compared with dangerous opioid alternatives.

- The FDA has asked for clarification around a chloroform impurity which is a process element in the manufacturing of methoxyflurane.

  MVP's new manufacturing technology meets the globally accepted standard for chloroform and MVP believe it can comply with the FDA's acceptable limits.

- The FDA raised questions about the "Instructions For Use" material for the Penthrox device (whistle).

  MVP believes it can satisfy the FDA in this regard.

- The FDA requires additional information about the variability of concentrations of the administration of methoxyflurane from closing the dilutor hole in the whistle.

  MVP believes it can supply the additional information the FDA requires.

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- The FDA questioned the amount/volume of methoxyflurane captured in the activated carbon device (the AC Chamber device which fits on top of the whistle), which is used to scavenge the smell and the exhaled methoxyflurane from a patient's breath. The FDA has asked for additional testing to demonstrate the absorption capacity of the AC Chamber.

  MVP believes it can satisfy this request.

- The FDA queried the performance of the inbuilt valve system within the whistle and asked a number of questions around the performance characteristics of these valves.

  MVP believes it can satisfactorily respond to the FDA's questions.

The FDA has advised of other issues which do not form part of its "Clinical Hold" Statement. The issues to be addressed include:

- The inadvertent exposure of methoxyflurane to healthcare professionals.
- Minor amendments to the labelling suggested in our application.
- Additional analytical tests to be used for both release and stability control testing.
- Amendments to acceptance criteria of impurities in the finished product of methoxyflurane.
- Additional biocompatibility testing for the whistle itself.

MVP believes it can satisfactorily respond to these issues.

MVP's CEO Mr. John Sharman said: "We are currently consulting with our scientific team, USA and EU advisors on the development program needed to satisfy the FDA's requirements. We will report back to the market as to the impact on costs and timeframes in due course."

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About PENTHROX®

PENTHROX® (methoxyflurane) is the only small, lightweight, handheld, fast-acting, inhaled analgesic that is self-administered under the supervision of the treating healthcare practitioner, indicated for the short-term relief of moderate to severe pain, associated with trauma or interventional medical procedures, in conscious adult patients. PENTHROX® provides rapid, effective pain relief in 5 minutes, with no need for needles and is not classified as an opioid. PENTHROX® allows patients to control their own pain relief by moderating the amount of PENTHROX® inhaled[1].

About Medical Developments International Ltd

MDI is an Australian company delivering emergency medical solutions dedicated to improving patient outcomes. MDI is a leader in emergency pain relief and respiratory products. The Company manufactures PENTHROX®, a fast-acting trauma & pain relief product. It is used in Australian Hospitals including Emergency Departments, Australian Ambulance Services, the Australian Defense Forces, sports medicine and for analgesia during short surgical procedures such as Dental and Cosmetic surgery as well as in other medical applications. MDI is expanding internationally and manufactures a range of world-leading Asthma respiratory devices.

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