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MEDIA RELEASE

PAEDIATRIC INDICATION FOR PENTHROX APPROVED BY HPRA

Medical Developments International (ASX: MVP) today announced that Health Products Regulatory Agency (HPRA), as the Reference Member State for the EU Decentralised Procedure (DCP), has approved the extension of the indication for Pentrox to include children aged 6 years and older from the prior indication of 18 years and older.

HPRA's medicines approval allows for national regulatory approval by member states (Ireland, France, UK, Austria, Czech Republic, Denmark, Finland, Croatia, Iceland, Norway, Sweden, Slovenia and Slovakia) and an application for device approval. Device approval is required as Pentrox is a combination product (medicine and device). All regulatory approvals are expected within 12 months.

Extension of the indication will broaden the addressable market for Pentrox.

CEO, Brent MacGregor said, *"After several years of hard work on the MAGPIE paediatric trial and the regulatory submission, we are thrilled to have received approval from HPRA to extend the use of Pentrox to children. We expect national approvals to follow. Extension of the indication expands the addressable market for Pentrox and will resolve one of the barriers to entry we have had in select ambulance trusts in the UK."*

About Medical Developments International Ltd

MVP is an Australian company delivering emergency medical solutions, including pain relief and respiratory products, and is dedicated to improving patient outcomes. The Company manufactures Pentrox®, a nonopioid trauma & emergency pain relief product. It is approved in Australia for pain relief in settings such as hospitals, ambulance services and short procedures, in accordance with the approved Product Information.

Media Enquiries

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