

PainChek Infant achieves regulatory clearance in multiple International markets

HIGHLIGHTS

- International regulatory clearances including CE Mark and the UK MHRA now received allowing sales and marketing of PainChek Infant in Australia, Europe, UK, Canada, Singapore and New Zealand.
- Clearances follow supportive findings of a clinical study of infants undergoing painful procedures
- PainChek now entering the large 400m¹ pre-verbal children worldwide with a novel app for Infants
- Infant App broadens the PainChek product portfolio with significant positive effect on global market entry into the larger Home Care and Hospital markets

PainChek® Ltd (ASX: PCK) (“PainChek®” or “the Company”), developer of the world’s first smart phone-based pain assessment and monitoring application, is pleased to announce it has received the necessary regulatory clearances including the CE Mark and UK MHRA that allow for sales and marketing of its PainChek Infant offering in Australia, Europe, UK, Canada, Singapore and New Zealand.

The regulatory clearances follow completion of the PainChek’s Infant Face-Only study, which demonstrated positive findings and is being peer-reviewed for publication. Findings from the study support the clinical indication for procedural pain assessment and PainChek infant is now cleared for use with infants aged between 1 month to 12 months.

PainChek will now progress with launch plans for PainChek infant in these markets and will pursue opportunities in the key Hospital and Home Care markets, with potential users including children’s hospitals, post-natal wards, parents and other healthcare professionals.

With 400 million pre-verbal children¹ in the world, of which it is estimated 100 million are born to first time parents, PainChek Infant is now able to access a very large new market opportunity.

The Company will also continue to expand the PainChek clinical applications and broaden the age ranges for Children’s pain assessment through additional research and clinical studies including the existing study at the Royal Children’s Hospital (RCH) in Melbourne.

PainChek® CEO Philip Daffas said:

“We’re delighted to achieve this regulatory milestone ahead of schedule and continue to expand PainChek’s global markets. The PainChek Infant App is unique in that it completes a microfacial analysis through a 3 second video assessment and provides the carer with an instant result in relation to the infant’s pain severity level.

PainChek now assesses and automatically documents pain scores for adults who cannot verbalise, adults who can self-report and now infants. PainChek is rapidly becoming a universal pain assessment system for all people, everywhere.

Having established the initial PainChek Adult App and the business model in aged care, this broad portfolio of offerings provides the foundation for our global market entry into the larger home care and the hospital markets. It's a truly exciting time for the Company".

Existing clinical paper-based tools to assess pain for pre-verbal children, such as the FLACC², have been available for some time, however they are rarely used in clinical practice with clinicians and nurses often relying on clinical observations to assess pain of which the infant's facial expressions are the most critical. High levels of exposure to painful face expressions can lead to observer bias, with some healthcare professionals showing an exaggerated underestimation of pain³. PainChek Infant's automated facial analysis addresses this problem.

The PainChek infant Face-Only study was developed to test the feasibility of using PainChek Infant's face domain alone as an indicator of pain, and to evaluate it using video recordings of infants undergoing painful procedures. The study involved PainChek Infant face domain scores being compared with assessments conducted using the Revised Neonatal Facial Coding System (NFCS-R) and the Observer Visual Analogue Scale (ObsVAS). Both NFCS-R and ObsVAS are well known and validated scales used in assessing procedural pain in infants, such as vaccinations, finger and heel pricks, dressing changes or more invasive procedures such as biopsies. Findings from the study supported the validity and reliability of PainChek Infant for procedural pain assessment. Procedural pain represents a significant problem as it can have both short-term and long-term negative consequences on children's health if not managed effectively.

This release has been authorized for release by CEO Philip Daffas.

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¹ See PCK ASX March 2021 quarterly results

² <https://www1.health.gov.au/internet/publications/publishing.nsf/Content/triageqrg~trriageqrg-pain~trriageqrg-FLACC>

³ Prkachin KM. Facial pain expression. Pain Manage 2011; 1: 367–76.

About PainChek®

PainChek® Ltd is an Australian based company that develops pain assessment technologies.

PainChek® is a smart phone based medical device using artificial intelligence to assess and score pain levels in real time and update medical records in the cloud. PainChek® records a short video of the person's face and analyses the images that indicate pain and records them.

Next, the caregiver uses PainChek® to record their observations of other pain related behaviours that complete the assessment. Finally, PainChek® calculates an overall pain score and stores the result allowing the caregiver to monitor the effect of medication and treatment over time.

PainChek® is being rolled out globally in two phases: first, PainChek® for adults who are unable to effectively verbalise their pain such as people with dementia, and second, PainChek® for Children who have not yet learnt to speak.

The PainChek® Shared Care Program is a PainChek® licensing model which enables a professional carer to share their resident or patient data securely with other healthcare professionals or designated homebased family carers for ongoing pain assessments or clinical data review.

To find out more, visit www.painchek.com