

## PainChek receives CE Mark and TGA clearance for Universal app

### HIGHLIGHTS

- PainChek has received CE Mark and Therapeutic Goods Administration (TGA) clearance for its expanded PainChek Universal app
- The regulatory clearances will enable marketing and sales of PainChek Universal across Europe, the United Kingdom and Australia as well as in Canada, Singapore and New Zealand
- PainChek Universal incorporates existing PainChek technology with the Numeric Rating Scale (NRS) pain score system traditionally used in healthcare settings
- PainChek Universal now allows ALL patients to have their pain monitored and managed by PainChek, not just those with dementia.
- Approval will substantially broaden PainChek's market, accelerate adoption by new clients and support retention of existing clients
- Universal app is now available for new users and will provide a system upgrade for existing PainChek clients
- Universal app provides data and insight for clinicians to make more informed pain management decisions

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 its Universal Pain Assessment Solution ("Universal") has received CE Mark clearance in Europe and the United Kingdom, and Therapeutic Goods Administration clearance in Australia.

Based on market feedback and client demand, PainChek expanded the utility of its PainChek app to include the Numeric Rating Scale (NRS), an established standard used to document self-reported pain levels in patients who can self-report. The combination of PainChek and the NRS in the Universal app allows carers to assess and manage pain for patients who cannot verbalise their pain and also now document and manage the pain score of those who can self-report their pain.

CE Mark and TGA clearance for the Universal app allows PainChek to market and sell it in Europe, the UK and Australia, in addition to Canada, Singapore and New Zealand, and provides functionality for a larger audience across aged care as well as in hospitals and for home care patients.

#### **PainChek® CEO Philip Daffas said:**

"Historically, PainChek® and NRS have been separate pain assessment processes in terms of function and documentation, as we initially developed PainChek to be used in situations where patients could not reliably verbalise their pain. We have now improved the process by incorporating the NRS into the PainChek® app, combining the benefits of the two pain scales into one universal pain assessment and management solution.

"PainChek's Universal solution now opens up the technology to those who can self-report their pain or who may be fluctuating between verbal and non-verbal communication. It means that PainChek can become a single, simple and rapid point-of-care solution for healthcare professionals in assessing and documenting pain across all their patients,

in a broad range of settings including the larger home care and hospital care markets. Based on initial market feedback we expect this novel solution will be well received by our existing users and attract a wider global audience.”

The Universal app will also generate significant additional data on pain assessment outcomes and activity at individual, facility and group levels. This is presented through tailored dashboards to provide insights to clinicians to make important medical decisions on pain management and optimum therapeutic interventions.

PainChek will initially roll out the Universal app in Australia and the United Kingdom from April 2021 before moving onto mainland Europe and other overseas markets.

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

**For more information:**

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**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.

PainChek Universal® expands the utility of the PainChek app to include the Numeric Rating Scale (NRS), an established standard used to document self-reported pain levels. The combination of PainChek® and the NRS in the Universal app allows carers to assess pain for patients who cannot verbalise their pain and also now document the pain score of those who can self-report their pain.

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](http://www.painchek.com)