16 October 2025

Listings Compliance (Sydney)
ASX Limited
By email: ListingsComplianceSydney@asx.com.au

Dear Sir/Madam

PainChek Limited (**PCK** or the **Company**) **– Response to ASX Aware Query (Reference: 113596)**

We refer to your letter dated 14 October 2025 regarding the recent movement in the price of the Company's securities.

We respond to each of your queries as follows:

1. **Does PCK consider the following information, or any part thereof, to be information that a reasonable person would expect to have a material effect on the price or value of its securities?**

   1.1 That PCK has been granted a De Novo classification by the FDA for its PainChek Adult App.

   1.2 That the FDA has created a new product code "SGB" formally recognising PainChek as a medical device for pain assessment.

   Yes

2. **If the answer to question 1 is "no", please provide the basis of that view.**

   Not applicable

3. **When did PCK first become aware of the information referred to in question 1 above?**

   Tuesday, 7 October 2025 at 7.50 a.m. AEDT

4. **If PCK first became aware of the information referred to in question 1 before the date of the Announcement, did PCK make any announcement prior to that date which disclosed the information? If not, please explain why the information was not released to the market at an earlier time, commenting specifically on when you believe PCK was obliged to release the information under the Listing Rules 3.1 and 3.1A and what steps PCK took to ensure that the information was released promptly and without delay.**

   The Company was not aware of the outcome of the U.S. FDA's decision regarding the application for De Novo clearance until the date and time specified above. The entity requested a trading halt on the above date in order to have time to prepare an announcement and prompty released that announcement without delay on Wednesday, 8 October 2025.

5. **Please confirm that PCK is in compliance with the Listing Rules and, in particular, Listing Rule 3.1.**

   The Company confirms it is complying with the Listing Rules and, in particular, Listing Rule 3.1.

6. **Please confirm that PCK's responses to the questions above have been authorised and approved under its published continuous disclosure policy or otherwise by its board or an officer of PCK with delegated authority from the board to respond to ASX on disclosure matters.**

   The Company confirms this response has been authorised and approved by the undersigned in accordance with the Company's continuous disclosure policy.

Yours sincerely

Natalie Climo

Natalie Climo
Company Secretary
PainChek Limited

14 October 2025

Reference: 113596

Ms Natalie Climo
Company Secretary
PainChek Ltd

By email

Dear Ms Climo

PainChek Ltd ('PCK'): ASX Aware Letter

ASX refers to the following:

A. The trading halt requested by PCK and granted by ASX Limited ('ASX') pre-market open on 7 October 2025 pursuant to Listing Rule 17.1 pending the release of an announcement regarding regulatory clearance from the U.S. Food and Drug Administration ('FDA') (the 'Trading Halt').

B. PCK's announcement titled 'Landmark FDA De Novo Grant received for PainChek's Pain Assessment App which opens up initial US$100 million per annum addressable market opportunity in the US' (the 'Announcement') released on the ASX Market Announcements Platform ('MAP') at 10:59 AM AEDT on 8 October 2025, which disclosed (among other things) that PCK has been granted a De Novo classification by the FDA for its PainChek Adult App.

C. The change in the price of PCK's securities from a closing price of $0.059 on 2 October 2025 to an intraday high of $0.083 on 6 October 2025, the day prior to PCK requesting the Trading Halt.

D. Listing Rule 3.1, which requires a listed entity to immediately give ASX any information concerning it that a reasonable person would expect to have a material effect on the price or value of the entity's securities.

E. The definition of "aware" in Chapter 19 of the Listing Rules, which states that:

> *an entity becomes aware of information if, and as soon as, an officer of the entity (or, in the case of a trust, an officer of the responsible entity) has, or ought reasonably to have, come into possession of the information in the course of the performance of their duties as an officer of that entity.*

F. Section 4.4 in Guidance Note 8 *Continuous Disclosure: Listing Rules 3.1 – 3.1B* titled "When does an entity become aware of information?"

G. Listing Rule 3.1A, which sets out exceptions from the requirement to make immediate disclosure as follows.

> *3.1A Listing rule 3.1 does not apply to particular information while each of the following is satisfied in relation to the information:*
>
> *3.1A.1 One or more of the following 5 situations applies:*
>
> - *It would be a breach of a law to disclose the information;*
> - *The information concerns an incomplete proposal or negotiation;*
> - *The information comprises matters of supposition or is insufficiently definite to warrant disclosure;*
> - *The information is generated for the internal management purposes of the entity; or*

- *The information is a trade secret; and*

3.1A.2 The information is confidential and ASX has not formed the view that the information has ceased to be confidential; and

3.1A.3 A reasonable person would not expect the information to be disclosed.

H. The concept of "confidentiality" detailed in section 5.8 of Guidance Note 8 *Continuous Disclosure: Listing Rules 3.1 – 3.1B*. In particular, the Guidance Note states that:

> *Whether information has the quality of being confidential is a question of fact, not one of the intention or desire of the entity. Accordingly, even though an entity may consider information to be confidential and its disclosure to be a breach of confidence, if it is in fact disclosed by those who know it, then it is no longer a secret and it ceases to be confidential information for the purposes of this rule.*

Request for information

Having regard to the above, ASX asks PCK to respond separately to each of the following questions:

1. Does PCK consider the following information, or any part thereof, to be information that a reasonable person would expect to have a material effect on the price or value of its securities?

   1.1 That PCK has been granted a De Novo classification by the FDA for its PainChek Adult App.

   1.2 That the FDA has created a new product code "SGB" formally recognising PainChek as a medical device for pain assessment.

2. If the answer to any part of question 1 is "no", please advise the basis for that view.

3. When did PCK first become aware of the information referred to in question 1 above?

4. If PCK first became aware of the information referred to in question 1 before the date of the Announcement, did PCK make any announcement prior to that date which disclosed the information? If not, please explain why the information was not released to the market at an earlier time, commenting specifically on when you believe PCK was obliged to release the information under Listing Rules 3.1 and 3.1A and what steps PCK took to ensure that the information was released promptly and without delay.

5. Please confirm that PCK is in compliance with the Listing Rules and, in particular, Listing Rule 3.1.

6. Please confirm that PCK's responses to the questions above have been authorised and approved in accordance with its published continuous disclosure policy or otherwise by its board or an officer of PCK with delegated authority from the board to respond to ASX on disclosure matters.

When and where to send your response

This request is made under Listing Rule 18.7. Your response is required as soon as reasonably possible and, in any event, by no later than **5:00 PM AEDT Friday, 17 October 2025**.

You should note that if the information requested by this letter is information required to be given to ASX under Listing Rule 3.1 and it does not fall within the exceptions mentioned in Listing Rule 3.1A, PCK's obligation is to disclose the information 'immediately'. This may require the information to be disclosed before the deadline set out above and may require PCK to request a trading halt immediately if trading in PCK's securities is not already halted or suspended.

Your response should be sent by e-mail to **ListingsComplianceSydney@asx.com.au**. It should not be sent directly to the ASX Market Announcements Office. This is to allow us to review your response to confirm that it is in a form appropriate for release to the market, before it is published on the ASX Market Announcements Platform.

Suspension

If you are unable to respond to this letter by the time specified above, ASX will likely suspend trading in PCK's securities under Listing Rule 17.3.

Listing Rules 3.1 and 3.1A

In responding to this letter, you should have regard to PCK's obligations under Listing Rules 3.1 and 3.1A and also to Guidance Note 8 *Continuous Disclosure: Listing Rules 3.1 – 3.1B*. It should be noted that PCK's obligation to disclose information under Listing Rule 3.1 is not confined to, nor is it necessarily satisfied by, answering the questions set out in this letter.

Release of correspondence between ASX and entity

We reserve the right to release all or any part of this letter, your reply and any other related correspondence between us to the market under Listing Rule 18.7A. The usual course is for the correspondence to be released to the market.

Yours sincerely

ASX Compliance