

1 October 2021

Heavy Heart

This week I asked all key stakeholders one simple question ...

what's happening with Trikafta's journey through the PBAC process?

Here is what I now know ...

1. The reimbursement of Trikafta will not be considered at the November PBAC meeting as no Vertex submission has been received.
 - a. Vertex has until 12/11/21 to submit to the December PBAC Meeting.
 - b. If they miss this deadline they have until 23/12/21 to submit to the March PBAC Meeting.
2. Vertex has not submitted the paperwork for people with F508del/Minimal function mutations to access Trikafta.
 - a. The Department of Health pricing unit can complete the process immediately and 400 eligible people will have access to Trikafta by Christmas ... we are all waiting on Vertex.
 - b. The PBAC confirmed their funding recommendation was for all people with F508del/Minimal function mutations. There is no specific list of approved mutations and therefore no limit to the 'type' of minimal function mutation in the recommendation.

I need to express my dismay and verging on disbelief that Vertex has not provided a submission to the November PBAC. I am a horrified and justifiably angry that they have not acted in good faith and progressed Trikafta for a group of people (F/M) yet to benefit from a CFTR modulator.

It is criminal that 400 people with cystic fibrosis (CF) must be left languishing while a corporation focuses on shareholder value and power plays.

I can confirm that both the PBAC and the Department of Health have asked Vertex to resubmit Trikafta quickly for the remainder of people with one copy of the F508del mutation and to reconsider their decision not to proceed with Trikafta for those with F508del/Minimal function mutations.

I can also confirm that Minister Hunt met with Stuart Arbuckle, Executive Vice President and Chief Operating Officer at Vertex soon after the F/M recommendation went public to action the current recommendation.

These protestations have fallen on deaf, uncaring ears at Vertex and consequently the CF community's frustration and disappointment is totally justified.

So where to from here ...

1. I am meeting with Vertex on Wednesday 6 October, and I will report back again then.
2. CFA has organised a 'Town Hall' meeting with the Deputy Chair of the PBAC on 12 October at 6.00pm AEDT and this is a great chance for the CF community to ask the tough questions and get the straight answers from Jo Watson [LINK HERE](#).
3. And I hate to ask again but you must let Vertex know how you feel, tell them what these cruel unnecessary delays are doing to you and those you love. Send your messages to nickim@cfa.org.au and we will make sure they get to all the right people.

It is with a very heavy heart that I write this communique but please be assured CFA will not stop advocating for the rights of people with CF and we will not be deterred by craven commercialism ... this lack of empathy is criminal and must end.

Kind regards

A handwritten signature in black ink, appearing to read "Nettie Burke". The signature is fluid and cursive, with the first name "Nettie" being more prominent than the last name "Burke".

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