

Vaughan Gething AC/AM
Ysgrifennydd y Cabinet dros Iechyd a Gwasanaethau
Cymdeithasol
Cabinet Secretary for Health and Social Services



Llywodraeth Cymru
Welsh Government

Ein cyf/Our ref VG/01050/18

David John Rowlands AM
Chair - Petitions Committee
National Assembly for Wales
Cardiff Bay
Cardiff
CF99 1NA

SeneddPetitions@assembly.wales

17 April 2018

Dear David,

Thank you for your letter of 23 March regarding Petition P-05-797 about access to the cystic fibrosis medicine, Orkambi®.

As stated previously the All-Wales Medicines Strategy Group (AWMSG) had already contacted the pharmaceutical company, Vertex Pharmaceuticals and strongly encouraged them to make a submission for appraisal. Whilst Vertex has agreed in principle to submit clinical data for appraisal by AWMSG, they have not committed to any firm date for doing so. If the manufacturer refuses to provide evidence about how well their medicine works, AWMSG cannot appraise it and cannot therefore issue a recommendation to make the medicine routinely available or not. There have been discussions with Vertex on the most effective approaches to appraisal for the additional license extensions for Orkambi® to treat different types of cystic fibrosis, due to come on-stream over the next few years but no appraisal can be carried out without evidence of the medicine's efficacy.

My officials have informed AWMSG that additional longer term clinical data appears to be available and AWMSG have subsequently contacted Vertex again. However, I repeat, the onus is on Vertex to submit their evidence for appraisal. I am at a loss to explain why Vertex have not already sent any evidence - existing or new - to AWMSG for appraisal.

Bae Caerdydd • Cardiff Bay
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Rydym yn croesawu derbyn gohebiaeth yn Gymraeg. Byddwn yn ateb gohebiaeth a dderbynnir yn Gymraeg yn Gymraeg ac ni fydd gohebu yn Gymraeg yn arwain at oedi.

We welcome receiving correspondence in Welsh. Any correspondence received in Welsh will be answered in Welsh and corresponding in Welsh will not lead to a delay in responding.

I will keep the Petitions Committee updated on developments.

Yours sincerely,

A handwritten signature in black ink that reads "Vaughan Gething". The signature is written in a cursive style with a large initial 'V'.

Vaughan Gething AC/AM

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Cabinet Secretary for Health and Social Services