

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



Llywodraeth Cymru  
Welsh Government

Our ref VG/03423/18

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

[SeneddPetitions@assembly.wales](mailto:SeneddPetitions@assembly.wales)

7 November 2018

Dear David,

Thank you for your letter of 16 October regarding Petition P-05-797 about access to the cystic fibrosis (CF) medicine, Orkambi® (lumacaftor/ivacaftor).

I note the proposal from the Cystic Fibrosis Trust to carry out a pilot project using the UK CF Registry to collect data to monitor the clinical impact of Orkambi® on patients, in addition to the clinical trials conducted previously. Registry data can help us understand the real world outcomes of innovative treatments and I therefore welcome the Trust's offer.

As the Trust acknowledges, any such project would need to be "underpinned by an acceptable interim commercial access arrangement". It would be necessary for any commercial arrangement to reflect the significant uncertainty identified by NICE in its appraisal of Orkambi®. Furthermore an agreement would need to ensure the price NHS Wales pays for Orkambi® could be considered to be within the bounds of what would normally be considered cost-effective by NICE and other UK appraisal bodies, and which is accepted by the UK pharmaceutical industry.

You will no doubt be aware that, to date, the manufacturer Vertex Pharmaceuticals Ltd has only proposed a commercial agreement that covers Orkambi®, several other licensed CF medicines, and as many as 18 medicines which have not yet been licensed or appraised. This portfolio approach has been rejected in all parts of the UK.

Bae Caerdydd • Cardiff Bay  
Caerdydd • Cardiff  
CF99 1NA

Canolfan Cyswllt Cyntaf / First Point of Contact Centre:  
0300 0604400

[Gohebiaeth.Vaughan.Gething@llyw.cymru](mailto:Gohebiaeth.Vaughan.Gething@llyw.cymru)  
[Correspondence.Vaughan.Gething@gov.wales](mailto:Correspondence.Vaughan.Gething@gov.wales)

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.

It is for Vertex to decide whether it wishes to enter into a specific commercial arrangement for Orkambi® with the NHS in Wales, taking account of the uncertainties and anomalies identified by NICE. Any arrangement would require a clear and binding commitment to engage in a future health technology appraisal by NICE or the All-Wales Medicines Strategy Group (AWMSG) within a specified time (normally 12 months). As it stands I have yet to see any tangible evidence that Vertex is willing to move on these important issues

Yours sincerely,

A handwritten signature in black ink, reading "Vaughan Gething". The signature is written in a cursive style with a large initial 'V' and a long, sweeping tail.

**Vaughan Gething AC/AM**

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Cabinet Secretary for Health and Social Services