



Eich cyf/Your ref
Ein cyf/Our ref DC/VG/06100/19

Mr David Ramsden
Chief Executive
Cystic Fibrosis Trust
Second Floor
One Aldgate
London
EC3N 1RE

rebecca.brooker@cysticfibrosis.org.uk

7 August 2019

Dear Mr Ramsden,

Thank you for meeting on 17 July, along with your colleague Anna Evans, and your subsequent letter of 23 July. We covered a good deal of ground and I considered it to be a very constructive meeting.

We agreed the importance of all medicines being subject to the established appraisal process to ensure the medicines the NHS uses are clinically and cost-effective. During the meeting, I confirmed that whilst Vertex Pharmaceuticals had not yet submitted their medicines Orkambi® or Symkevi® for appraisal by the All Wales Medicines Strategy Group (AWMSG), they had written to me confirming their intention to do so. This follows Vertex's earlier commitment and repeated attempts by AWMSG to engage with them. I remain hopeful they will now engage.

I confirmed AWMSG would usually issue a Statement of Advice to advise the NHS that a medicine should not be routinely available where it has not been appraised. In relation to Orkambi® and Symkevi® these statements have not yet been published whilst my officials' and AWMSG's continued to engage with Vertex. As agreed, I attach an annex listing the various engagement between my officials, the NHS and Vertex dating back to 2016. Given all reasonable engagement has now concluded, it is for Vertex to submit their medicines for appraisal; if they do not do so, AWMSG will issue Statements of Advice to the NHS, in line with their procedures which are accepted by all other manufacturers.

The Chief Pharmaceutical Officer confirmed that the Welsh Government had responded to queries from Vertex about various details of the appraisal process and outlined how the NHS would reasonably expect that the price of a medicine should reflect any uncertainty about its clinical effectiveness.

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

Bae Caerdydd • Cardiff Bay
Caerdydd • Cardiff
CF99 1NA

Gohebiaeth.Vaughan.Gething@llyw.cymru
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.

AWMSG arranged a teleconference with Vertex on 11 July to discuss the patient access schemes required until the uncertainty about the medicines' clinical effectiveness is removed by the completed appraisals. Vertex subsequently cancelled the meeting at short notice and it has not yet been rescheduled.

I can confirm AWMSG has agreed to appraise Orkambi® for paediatric patients (aged 2-11). Vertex has asked AWMSG to appraise Orkambi® for older patients as well. However, because NICE has already appraised Orkambi® for this group of patients, AWMSG would not normally repeat this work unless Vertex could offer significant new evidence. AWMSG would need to see any such evidence before starting an appraisal, so that they could decide if it were so significant that the medicine merited a new appraisal.

As you know, the Scottish Medicines Consortium (SMC) is currently appraising Orkambi® and Symkevi® and is expected to publish their recommendations on 12 August. If the SMC recommend either medicine, and Vertex offer an appropriate patient access scheme, the NHS in Wales would be able to move quickly to consider whether interim arrangements for these medicines would be appropriate, in order to make these medicines available to patients.

I wrote to Vertex shortly after our meeting to press once again for their engagement in our appraisal process; neither I nor AWMSG have as yet had a response.

Yours sincerely,

A handwritten signature in black ink that reads "Vaughan Gething". The signature is written in a cursive, slightly slanted style.

Vaughan Gething AC/AM

Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol
Minister for Health and Social Services

Annex: Engagement with Vertex Pharmaceuticals

Date	Engagement
May 2016	AWMSG asked Vertex to submit Orkambi® for adult patients for appraisal.
March 2017	AWMSG repeated their request.
May 2017	Vertex had not indicated they would make a submission to AWMSG
Nov 2017	AWMSG asked Vertex to submit Orkambi® for paediatric patients for appraisal.
Dec 2017	AWMSG repeated their request.
March 2018	AWMSG asked Vertex to submit Symkevi® for appraisal.
April 2018	AWMSG contacted Vertex again about appraising Orkambi®, following claims to the Assembly's Petitions Committee that Vertex had new evidence about its clinical effectiveness.
May 2018	Vertex asked for a meeting with the Minister.
June 2018	The Minister refused Vertex's request for a meeting, and urged them to engage with the appraisal process.
July 2018	Vertex wrote to the Minister with an update.
Aug 2018	Vertex wrote to AWMSG; AWMSG responded by reiterating that medicines must go through the appraisal process. Welsh Government had a meeting with AWMSG to discuss Orkambi®.
Sept 2018	The Minister wrote to Vertex to encourage engagement with the appraisal process.
Nov 2018	AWMSG repeated their request to Vertex to submit Orkambi® and Symkevi® for appraisal.
Jan 2019	Vertex wrote to AWMSG, who replied by outlining the appraisal process. This was followed up with a phone call.
Feb 2019	Vertex and Welsh Government had a telecon to discuss the appraisal process and Vertex raised some queries about the process.
March 2019	AWMSG provided Vertex with the information Welsh Government had requested on their behalf. Welsh Government asked AWMSG to delay publishing the Statements of Advice about Orkambi®, Symkevi® and Kalydeco®.
April 2019	Welsh Government wrote to Vertex with information about the appraisal process, and encouraging them to submit Orkambi® and Symkevi® for appraisal.
May 2019	Vertex wrote to Welsh Government about interim access and Welsh Government asked them to submit Orkambi® and Symkevi® for appraisal.
June 2019	Vertex wrote to the Minister to say that they would ask AWMSG to appraise Orkambi® for all age groups and Symkevi®.
July 2019	The Minister replied, welcoming Vertex's decision to submit Orkambi® and Symkevi® to AWMSG for appraisal.