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Email only

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Dear Simon,

Clarification of NICE's methods for technology appraisals

Thank you for Vertex's participation in the meeting on Friday 30 November 2018 with Sir Andrew Dillon in attendance.

It is important for me to emphasise at the outset the need for consistency in our work, from one appraisal to another. Cystic fibrosis and the treatments you have developed have a unique set of characteristics but we need to demonstrate that we have applied our methods in a way that neither advantages nor disadvantages other diseases and conditions, and their treatments.

You asked us to clarify our position on the discount rate used in NICE appraisals in general, and in the appraisal of your treatments for cystic fibrosis in particular. You noted that the 'Green Book' published by HM Treasury, which is referred to in our methods guide, now suggests the use of a 1.5% rate for health interventions.

The discount rate we use is based on the advice set out in the Green Book, but it is set following consultation with our stakeholders, including the Department of Health and Social Care, and NHS England. The rate we apply, currently 3.5% for both costs and benefits, has both policy and financial implications, which need to be taken into account in deciding the actual rate to be applied. It is important, therefore, that before we make any change, we subject any proposal to do so to formal consultation.

We discount costs and benefits at the same rate because the costs incurred in acquiring a new treatment is money which otherwise would be used to generate health benefits elsewhere in the NHS. This is consistent with the approach taken by the Department of Health and Social Care in its own economic analyses.

As we have previously indicated, a discount rate of 1.5% can be used in the special circumstances set out in our methods guide. This would be where a treatment restores people, who would otherwise die or have a severely impaired life, to full or near full health.

Our independent appraisal committee did not consider that these conditions applied in the case of lumacaftor-ivacaftor. However, if the data for your forthcoming triple therapy is indeed as persuasive as you say it is, it is possible that the committee will apply the lower discount rate in that appraisal. I should emphasise that for a firm and final decision on this to be taken, it is essential that you engage your new treatments in the NICE appraisal process.

Turning to the second of the two topics we discussed on 30 November, you asked whether NICE would be able to consider an offer that provides an 85% discount on the list price for all drugs in Vertex' portfolio after 13 years (that is, from 2031).

In my letter of the 9 October, I referred you to the fact that the Appraisal Committee has already indicated why it could not take this into account (see paragraph 4.18 of TA 398). At the meeting on the 30 November, you asked us to clarify whether, if positioned as an offer, rather than a modelling assumption, it would be then feasible for NICE to consider it.

The NICE methods guide indicates that where the Appraisal Committee is asked to consider analyses based on price reductions for the NHS, they may only do so if the price is transparent and consistently available across the NHS, and if the period for which the specified price is available is guaranteed. In practice, this means that we will only accept a reduced price if it is referred to NICE by the Department of Health and Social Care for offers made before 1 January 2018, and NHS England for offers after that date. As we pointed out at our meeting, we have not received a referral in this case.

NHS England has indicated that it would not refer an offer to NICE where the benefits to the NHS are no more than what would otherwise be expected from generic competition, and where the effect of the offer is to add those savings to the upfront value, and therefore the price, of its medicine. NHS England has indicated that to accept an offer of this kind would be inconsistent with the principle of allowing a period of market exclusivity, during which the company is allowed to charge a monopoly price at full value, on the understanding that the NHS will get the benefit from generic competition when that arrives.

From NICE's perspective, even if NHS England were to refer an offer of this kind for consideration, we expect the Appraisal Committee to ask how likely is it that the proposed savings will actually be made, and how reasonable is it therefore to add them to the upfront value of the medicine? The Appraisal Committee will have to take into account that by the time the savings are expected to be made, it is highly likely that most patients will be receiving triple therapy. Indeed, we cannot be certain what other treatments may be available at that point, and what therefore will be the standard of care.

We hope this clarification is helpful and we look forward to your decision on re-engaging with us in the appraisal of tezacaftor-ivacaftor, the review of lumacaftor-ivacaftor, including consideration of new patient groups, and the forthcoming triple therapy.

Kind regards,

Meindert Boysen

Director, Centre for Health Technology Evaluation

CC. John Stewart, National Director, Specialised Commissioning, NHS England