Sent by e-mail only: XXXXXXXXXXXXXXXXX

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Women's and Children's Academic Health

Kings College London

Becket House

1 Lambeth Palace Road

London

SE1 7EU

18 August 2023

Dear XXXXXXXXXXXXX and XXXXXXXXXXXXXXX,

**Re: Final Appraisal Document — Voxelotor for treating haemolytic anaemia caused by sickle cell disorder (SCD) (ID1403)**

Thank you for your letter of 10 August 2023.

I have considered your letter carefully and note your concerns.

I note that you say the NHP would like to appeal against the decision not to recommend voxelotor in the above appraisal. I have therefore considered your letter of 10 August 2023 as lodging an appeal against the above Final Draft Guidance (FDG).

I hope it assists for me to draw your attention to NICE's *Guide to the technology appraisal and highly specialised technology appeal process* (the "[Appeal Process Guide](https://www.nice.org.uk/process/pmg41/chapter/making-an-appeal)") [PMG41] sets out what an appeal letter must contain. In particular, at 4.6:

*"The appeal letter must clearly and concisely set out the appellant's points of appeal in detail. Appeal points must be made in order of the ground to which they relate, that is, all appeal points made under ground 1(a) must be made first, followed by all points made under ground 1(b) and then all appeal points made under ground 2. Appeal letters must provide enough information for the appeal panel to understand all points being raised.*

*Each point must be headed with the appeal ground to which it relates, and a 1‑sentence description of the appeal point. For example, 'Ground 1(a).1: the change from a positive to negative recommendation following draft guidance without further consultation is unfair'.*

*Each appeal point must be numbered so that the first appeal point under ground 1(a) is numbered 1(a).1 with subsequent ground 1(a) points numbered 1(a).2, 1(a).3, and so on. The same numbering will apply for ground 1(b) and ground 2 points, for example: 1(b).1, 1(b).2, 2.1 and so on.*

*…*

*In summary the appeal letter must include the following information:*

* *the ground(s) of appeal*
* *the aspect(s) of the final draft guidance, or technology appraisal or highly specialised technologies evaluation process, being appealed against*
* *the reasons why the aspect(s) of the final draft guidance, or technology appraisal or highly specialised technologies evaluation process, being appealed against fall within the specified ground(s) of appeal, in enough detail to demonstrate an arguable case*
* *the concluding statement indicating whether the appellant wishes to be heard at an oral or written appeal.*

On receipt of an appeal letter, the Institute's appeal procedures provide for an initial scrutiny of points that an appellant wishes to raise, to provide an initial view on whether they are within the permitted grounds of appeal ("valid") and are at least arguable. The permitted grounds of appeal are:

* 1(a) NICE has failed to act fairly, or
* 1(b) NICE has exceeded powers;
* (2) the recommendation is unreasonable in the light of the evidence submitted to NICE.

Unfortunately, in this case, I cannot identify any specific appeal points under the relevant grounds of appeal from your letter of 10 August 2023. I have therefore been unable to provide my initial views on whether your letter presents any arguable point(s) of appeal.

You are, however, entitled to submit **further clarification and/or evidence to me within the next 10 working days** and I invite you to take this second opportunity to submit specific appeal points under NICE's grounds of appeal in response to this letter. I will then confirm whether you have made any valid appeal points that will be referred to the Appeal Panel.

Again, if you would like your appeal to be considered please respond to this letter **within the next 10 working days** ensuring that you meet the requirements set out in the Appeal Process Guide.

Once I have made my final decision, and where there is more than one appellant, each appellant will receive the valid appeal points of the other appellants and their redacted appeal letter. This is to enable appellants to avoid duplication at the hearing where there are overlapping appeal points. If the appeal letter and/or responses to scrutiny contain confidential information please ensure you have provided a version with this information redacted by 1 September 2023.

Ordinarily appeals are conducted on the basis of the appellants’ written appeal letters, and the material generated during the appraisal process. Use of additional written material is discouraged, and the panel cannot receive any new evidence. If, exceptionally, you feel there is written material that will not be before the panel that you would wish to rely on you must let the NICE Appeal team know by return of letter, indicating what the material is, why it is desirable to submit it, and when it will be available, by no later than 4 September 2023. Please note that the appeal panel cannot accept papers that are tabled late or ad hoc, as this affects the preparation of the panel and other parties for the appeal.

Yours sincerely

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Dr Mark Chakravarty

Lead Non-Executive Director for Appeals & Vice Chairman

National Institute for Health and Care Excellence