Sent by e-mail only: XXXXXXXXXXX

FAO XXXXXXXXXX

Royal College of Physicians

10 May 2024

Dear XXXXXXX

**Re: Final Draft Guidance – Fenfluramine for treating seizures associated with Lennox-Gastaut Syndrome in people 2 years and over (ID1651)**

Thank you for your letter of 2 May 2024, lodging an appeal against the above Final Draft Guidance (FDG). I acknowledge your concerns with the decision not to recommend fenfluramine for treating seizures associated with Lennox-Gastaut Syndrome in people 2 years and over, however, as you have not raised any points under the permitted appeal grounds I am currently unable to take your concerns forward under the appeals process.

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.

These grounds of appeal are prescribed by legislation and NICE has a statutory duty under *The National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013* to allow a person to appeal a technology (or highly specialised technology) appraisal recommendation on the above grounds. Only if I am satisfied that your points contain the necessary information, are arguable, and fall within any one of the grounds will your appeal be referred to the Appeal Panel.

As you not identified any points under the above grounds I am unable to take your concerns forward. If you consider that your concerns fall within the permitted grounds I invite you to submit further details clarifying the grounds on which your appeal is made within the next 10 working days. I will then give a final decision on the points to be put before an appeal panel.

1. 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 3 June 2024.
2. 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 28 May 2024. 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

XXXXXXXXXX

Dr Mark Chakravarty

Lead Non-Executive Director for Appeals & Vice Chairman

National Institute for Health and Care Excellence