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Pierre Fabre Ltd

Via email

Dear

Final Appraisal Determination of Vinflunine for the treatment of advanced or metastatic transitional cell carcinoma of the urothelial tract

Thank you for your reply to my initial scrutiny letter. I have taken your comments into account and this letter is my final decision on initial scrutiny.

Before dealing with the appeal points, I note your comments concerning the production of a clinical guideline. That is a separate process to the production of a technology appraisal. I feel confident you will have the opportunity to make the points you would seek to make in an appeal to the Guideline Development Group in that process, and to engage broadly with the question of best care for patients with bladder cancer.

Ground 1

1.1. In formulating guidance, the Institute has been unfair by not responding to the findings of the previous appeal hearing and has continued to apply inconsistent data quality standards

I have considered your additional comments but I do not feel they have really addressed my concerns. In addition I feel the correct forum to address overall management of bladder cancer will be during the guideline development, with which I encourage you to engage.

As I do not agree this is a valid appeal point I will not be referring it to an appeal panel.

1.2. The Institute has been unfair in the economic evaluation of vinflunine for patients with urothelial cancer that relapse after prior chemotherapy

Although I have noted your comments concerning the scope, particularly where a previous appeal was upheld on the basis that the scope must be adhered to I cannot see there is any prospect of this argument succeeding.

As I do not agree this is a valid appeal point I will not be referring it to an appeal panel.

Ground 3

3.1 The institute has exceeded its powers by reviewing decisions made by the EMEA and MHRA and drawing different conclusions despite not having the data available or the qualifications to do so.

We are slightly at cross purposes. My previous letter sought to explain why NICE and the EMEA/MHRA have different remits, and why a different treatment of evidence was not a review of a decision of the EMEA or MHRA. I also explained why committees are entitled to choose the analyses they feel are most helpful, provided they are reasonable. I can see that there is scope for debate about which are the best analyses and what the data show, as my initial reply made clear, but I cannot see that this can amount to the Institute exceeding its powers.

As I do not agree this is a valid appeal point I will not be referring it to an appeal panel.

Conclusion

As I do not agree your appeal points are valid I am not at this stage passing them to an appeal panel for consideration. However your commitment to the overall care of bladder cancer patients is clear, and I welcome your seeking a constructive way forwards. I do hope you will continue to engage with these issues through the guideline development process which I think will offer the opportunity you are seeking.

Yours sincerely

Appeals Committee Chair
National Institute for Health and Clinical Excellence