

Sent by email

██████████  
General Manager  
Ferring Pharmaceuticals Ltd

4 June 2014

Dear ██████████

**Final Appraisal Determination: Degarelix for treating advanced hormone dependent prostate cancer**

Thank you for your letter of 23 May 2014. This letter is my final decision on initial scrutiny.

***Ground 1.3(a) The FAD recommendation is not sufficiently clear, precise or understandable for the NHS and is therefore not in accordance with the STA Guide or principles of good administration.***

Thank you for your additional information. In light of that information I agree this is a valid appeal point.

To assist you to prepare for the hearing, I would suggest that an appeal panel may wish to understand why it is that the current recommendation raises a real risk of use of Degarelix contrary to the SPC. I note that you say you have evidence of inappropriate switching. At initial scrutiny stage it is not appropriate for me to enquire closely into that. However it may be that an appeal panel would expect care of these patients to remain under the supervision of a specialist consultant based in a secondary care setting. It may assist the panel if you were ready to explain the evidence for a practical problem with non-specialist clinicians and/or in primary care.

I note that you accept my other suggestions, and therefore confirm the valid appeal points as 1.1(a), 1.2(a), 1.3(a), 2.1 and 2.2.

Yours sincerely

Dr Maggie Helliwell

Vice Chair of NICE

National Institute for Health and Care Excellence