FERRING
PHARMACEUTICALS

Dr Maggie Helliwell
Vice Chair of NICE
National Institute for Health and Care Excellence
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23rd May 2014

Dear Dr Helliwell

Thank you for providing your initial views on the points of appeal Ferring has raised. We very much appreciate the time you have taken to perform this initial scrutiny and are also grateful for the opportunity to comment on your letter to elaborate on or clarify any of the points raised.

While Ferring accepts the majority of your views, we would like to explain why we consider Ground 1.3(a) to be a valid ground for appeal and ask you to reconsider the admissibility of this ground.

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.

We maintain our position that the Appraisal Committee (AC) has not given adequate consideration to the likely implications of its guidance and consider that it would - in practice - be misleading and unworkable. Had the AC given full consideration to likely real world practice in regard to this part of the guidance, we do not believe that the AC would have been comfortable with the wording that it settled upon.

In your consideration, you made the following statement:

> *"I doubt there can be any argument with the sentiment proposed, either that recommended treatment must be within the terms of the SPC or that treatment should continue until the responsible clinician recommends that it should stop (or, of course, until the patient wishes to stop, if sooner). I would expect those points to be universally understood, so that there is no need to add them to an FAD. Even if that was not correct I could not agree that it was arguable that not spelling that understanding out made the guidance unclear.*
>
> *As the issue here is not on the substance of the guidance or the process by which it was produced, but whether to make explicit something which I believe is universally regarded as implicit, it is a question of the wording of the FAD only."*

We agree with you that following the SPC should be implicit. The degarelix SPC states that it is

indicated for advanced, hormone-dependent prostate cancer. The AC's recommendation means that treatment degarelix is likely to be initiated in circumstances that the SPC does not envisage, *i.e.* in the acute, emergency care setting. Nowhere does the SPC give advice on how to use the product in that setting. We have appealed the narrowness of the recommendation itself but, given that the approved SPC does not envisage use of degarelix solely in the emergency or acute care context, we consider it essential that the Institute gives appropriate guidance on use of the product as patients move from this setting to a use that is fully consistent with that envisaged by the SPC.

If the current guidance remains as it is, patients presenting with signs and symptoms of spinal cord compression would be regarded as being in an acute, emergency situation. The initial dose of degarelix will be effective for 1 month, by which time this emergency situation will most likely have been resolved and therefore could give rise to confusion, especially if the patient is discharged to primary care. We are clear that most non-specialist clinicians and NHS bodies do not recognise what is an undoubted difference between degarelix, a GnRH *antagonist,* and LHRH agonists, in terms of their mode of action and effects. As a result, there is a tendency to regard them as inter-changeable under the class of "hormone therapies."

In areas where health service providers have restricted use of Firmagon as the FAD envisages, we have seen evidence that patients are initiated on a single dose of degarelix and then switched. This is in a significant minority of CCGs, but does occur in the absence of appropriate guidance. The potential for switching was also clearly an issue of which the National Collaborating Centre for Cancer had in mind in its response to the ACD, where it suggested that the AC "*consider recommending a switch to an LHRH agonist after the man has been stabilised on degarelix*", but the Institute did not do so. Given the AC's current recommendation, and without specific guidance to the contrary, we would therefore expect that clinicians will assume that patients should be switched after that initial treatment, a use that is inconsistent with the SPC. Such a move would also be inconsistent with the basis for this HTA and unsupported by the evidence base because there are no long term data to show what impact this may have on the patient in terms of safety, symptom exacerbation, disease progression or overall survival.

Our concern over the inequality of access leading to the practice of switching was raised in a letter to [redacted], National Clinical Director for Cancer Services, in September of last year and I have copied the extract for your reference below:

> "GMMMG are maintaining the "red" status of degarelix which means that it can only be initiated in secondary care and not maintained in primary care, despite feedback from the committee that the clinical case for degarelix was proven at this review. This in turn means that either the patients have to be brought back into hospital to receive their maintenance doses, which appears totally contrary to one of the key objectives for the NHS (not to mention the inconvenience for the patient), or that non-evidenced based switching occurs in primary care where patients initiated on an antagonist are switched to an agonist, or that

the patient is denied degarelix because of the concern over the patient being switched in the community." Manchester is not the only region in the country where this practise occurs, and it is a source of immense frustration to the initiating clinician.

Hence, we firmly believe that if the guidance remains unchanged, the acute nature of the condition for which NICE is currently recommending the use of Degarelix, will lead to single dose usage in a substantial number of cases and potentially put patients at risk. We believe that this is inconsistent with the basis for this appraisal and neither in accordance with the STA Guide nor with the principles of good administration. Nor do we believe that our comments to the AC have been given due consideration.

With this in mind, we very much hope you will reconsider and conclude that Ground 1.3(a) is a valid ground for appeal.

Please let me know if you have any additional comments or queries, or if you require any additional information.

Yours sincerely

[redacted]
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