Royal College of Physicians
11 St Andrews Place
Regent's Park
London NW1 4LE
Tel: +44 (0)20 3075 1560

**www.rcplondon.ac.uk**

Dr Maggie Helliwell
Vice Chair of NICE
National Institute for Health and Care Excellence
c/o appeals@nice.org.uk

**From The Registrar**
[redacted]

17 June 2014

Dear Dr Helliwell

**Re: Initial scrutiny letter from NICE regarding the RCP appeal against the FAD Enzalutamide for metastatic hormone-relapsed prostate cancer previously treated with a docetaxel-containing regimen [ID600]**

The Royal College of Physicians (RCP) plays a leading role in the delivery of high quality patient care by setting standards of medical practice and promoting clinical excellence. We provide physicians in the United Kingdom and overseas with education, training and support throughout their careers. As an independent body representing close to 30,000 Fellows and Members worldwide, we advise and work with government, the public, patients and other professions to improve health and healthcare.

The RCP is grateful for your response to our recent appeal against the FAD for the above technology appraisal. We would like to respond to your letter as follows.

Referring to your comment:

> ***'1.1 Inclusion of paragraph 1.2 of the FAD is not fair***
> *I understand your argument to be that as paragraph 1.2 of the FAD states that the use of enzalutamide for patients previously treated with abiraterone is not covered by the guidance, there will be variation in the local commissioning of treatment for such patients. This variation makes the FAD unfair.*
> *It is apparent from the FAD that the Appraisal Committee carefully considered whether it could make a recommendation on the cost effectiveness of enzalutamide after treatment with abiraterone (see paragraph 4.23).*
> *The logical conclusion of your argument is that the Committee should recommend a treatment about which it had insufficient evidence to make a recommendation to ensure consistency in treatment across the country. I do not think that that would be appropriate, or that the Committee can be said to have acted unfairly by not taking the course of action you suggest.'*

We would respectfully highlight that the conclusion you have drawn is not what we are implying. The 'unfairness' is in NICE singling out in 1.2 of the FAD that previous treatment with abiraterone is not covered by this guidance. All we are trying to say is that 'fairness' would have been reflected had the section 1.2

been completely removed or the section should have stated that 'previous treatment with all other available therapies for mCRPC in the post-docetaxel setting are not covered by this guidance'.

We acknowledge and fully accept that the Committee can only make recommendations based on the evidence. However, by the very nature of different treatments coming out at different times the specific recommendation in 1.2 is in our opinion misjudged as it will create an artificial sequencing strategy which will not have any basis on the clinical judgement. As such, it will be more a reflection of trying to get the available treatments which are NICE approved but which have different caveats. As a simplified example of that, a patient getting Enzalutamide, based on this FAD being implemented, could still get Abiraterone after that (NICE technology appraisal guidance 259). However, a patient who had abiraterone first would not be able to get enzalutamide. Therefore, as we acknowledge that there is lack of evidence either way, we feel that removal of 1.2 would be the fair way to deal with this situation. Hence, we stand by our conviction that inclusion of section 1.2 of the FAD is not fair.

Keeping the section 1.2 as it currently stands is open to varied and differential interpretation by local commissioning and would result in the stated standards of implementing NICE guidance not being met, in particular the sections underlined below (in red):

'*Implementing NICE guidance offers benefits to patients and carers, healthcare professionals and organisations.*

*NICE guidance can help patients, carers and service users*

- *Receive care in line with the best available evidence of clinical and cost-effectiveness.*
- *Enable people to be accountable for their care, knowing how they will be cared for in a consistent evidence-based approach, thus building patients confidence in NHS services.*
- *Improve their own health and prevent disease.*

*NICE guidance can help health and social care professionals*

- *Ensure care provided is based on the best evidence available.*
- *Ensure clinicians meet the standards set by regulatory bodies and that they consider NICE guidance when using their clinical judgement.*
- *Enable all staff dealing with patient queries to have confidence in the approaches to care.*
- *Effectively target resources and efforts at the areas that offer the most significant health improvement.*

*NICE guidance can help organisations*

- *Meet the NHS Litigation Authority (NHSLA) risk management standards and benefit from reduced claims and risk management premiums.*
- *Enable and assist organisationswith forward planning for service provision and commissioning, ensure national priorities, set by NHS England and the Department of Health are reflected.*
- *Benefit from any identified disinvestment opportunities, cost savings or opportunities for re-directing resources.*
- *Meet government indicators and targets for health improvement and reducing health inequalities.*
- *Help local government fulfil its remit to promote the economic and social well-being of its communities.*

- *Provide a focus for multi-sector partnership working on health.'*

With the above in mind, we would be grateful if you would kindly reconsider your decision regarding Section 1.2 of the FAD (which we would preferably see deleted).

Yours sincerely

[redacted]
Registrar