Comments on the ACD Received from the Public through the NICE Website

Name	[redacted]
Role	Pharmaceutical Industry
Other role	Health Economics Manager
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	We welcome the opportunity to comment on the draft guidance for axitinib. The draft guidance recommends axitinib as follows: Axitinib is recommended as an option for treating adults with advanced renal cell carcinoma after failure of treatment with a first-line kinase inhibitor or a cytokine, only if the manufacturer provides axitinib with the discount agreed in the patient access scheme. The licence for axitinib is as follows: Axitinib is indicated for the treatment of adult patients with advanced renal cell carcinoma (RCC) after failure of prior treatment with sunitinib or a cytokine. We do not agree with the draft recommendation for two main reasons: ? The draft recommendation is not in line with the axitinib licence from the European Medicines Agency (EMA) ? It is beyond the remit of NICE to recommend a medicine outside of its marketing authorisation The draft recommendation by NICE clearly covers a broader population than the licensed population for axitinib and therefore not in line with the licence axitinib received from the EMA. Although the AXIS trial included patients that had received prior targeted therapies such as bevacizumab and temsirolimus, the efficacy of axitinib in this patient group was not proven. The EMA EPAR states that there is not adequate information on the use of axitinib after first line bevacizumab or temsirolimus treatment. The group of patients previously treated with temsirolimus and bevacizumab+IFN-α are very small (n=25 and n=59, respectively), and this resulted in inconsistencies in the efficacy results of axitinib across the subpopulations based on prior therapy. Therefore no firm conclusions can be made regarding the efficacy of axitinib in these subgroups. Due to these concerns, the licence for axitinib was limited to patients who had failed prior sunitinib or cytokine therapy. NICE?s remit requires that the Institute recommends medicines within their licensed indications. The draft recommendation is at odds with this remit. The updated scope released by NICE following the appeal clearly states that the remit or appraisal objective was to appraise the clinical and cost effectiveness of axitinib within its licensed indication for the treatment of advanced renal cell carcinoma after failure of prior systemic treatment. This remit has not been followed in this draft guidance. Â In addition, section 6.1.12 of the NICE Methods Guide 2013 states that: Â The Appraisal Committee does not normally make recommendations regarding the use of a drug outside the terms of its marketing authorisation???.Exceptionally, the Department of Health (DOH) may direct the Appraisal Committee to make recommendations about a technology outside of the terms of its marketing authorisation or instructions for use. As far as we are aware, there is no exceptionality

	that applies to this indication nor has NICE shared with stakeholders any communication from the DOH directing the Appraisal Committee to make a recommendation for axitinib outside of its licence. We therefore strongly believe that NICE has exceeded its powers by recommending axitinib outside of its licence. Everolimus is the only second line therapy that can be used in patients whose disease has progressed on or after treatment with VEGF-targeted therapy, in line with its licence that was supported by a robust phase 3 trial (RECORD1). We therefore urge NICE to issue a recommendation for axitinib that is within its licensed indication in line with NICE?s remit. References 1. Final NICE scope for axitinib: this can be accessed on: http://www.nice.org.uk/nicemedia/live/13688/65408/65408.pdf 2. Guide to the methods of technology appraisal 2013 http://www.nice.org.uk/media/D45/1E/GuideToMethodsTechnologyAppraisal2013.pdf 3. Axitinib European Public Assessment Report (EPAR). This can be accessed on: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Public_assessment_report/human/002406/WC500132190.pdf 4. Everolimus summary of product characteristics (smPC) ? accessed on: http://www.medicines.org.uk/emc/medicine/22281/SPC/Afinitor+Tablets/ 5. Axitinib summary of product characteristics (smPC) ? accessed on: http://www.medicines.org.uk/emc/medicine/27051/SPC/Inlyta+1+mg+3mg%2c+5+mg+%26+7mg+film-coated+tablets/
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	

Section 8 (Proposed date of review of guidance)	
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