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

Role	Pharmaceutical Industry
Location	England
Conflict	No
Comments on individual sections of the ACD:	
Section 4 (Consideration of the evidence)	Allergan requests NICE to revise section 4.15; BOTOX® at a 100U dose is an effective option for OAB shown to deliver meaningful benefits for patients who are inadequately managed with antimuscarinic drugs and has an acceptable safety and tolerability profile. BOTOX® 100U has been evaluated in large multicenter placebo-controlled phase III trials for OAB. The first accepted manuscript is published by the Journal of Urology at http://www.jurology.com/article/S0022-5347(12)05849-1/abstract. The dose would be different for other products as Botulinum toxins are not interchangeable. In the two pivotal phase III studies patients treated with 100U exhibited significant improvements in all OAB-related efficacy measures, translating into substantial HRQOL improvements. A positive opinion for BOTOX® 100U for OAB was received in Europe on 18/12/2012 via the Mutual Recognition Procedure with Ireland as the reference member state. An abstract describing the interim results of long-term safety and efficacy will be presented at the May 2013 American Urological Association congress.

Role	Other
Other role	UK Patient support group for bladder illness
Location	England
Conflict	No
Notes	The COB Foundation is the largest patient support charity for bladder illness in the UK. We support patients suffering with all forms of cystitis, overactive bladder and continence issues. Our membership patient database gives us direct information from those suffering with overactive bladder and we fully understand their treatment pathways and the current options available to them.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The COB Foundation supports the recommended treatment option of Mirabegron to those who cannot tolerate antimuscarinic drugs or for whom it proves ineffective. Â Our patient database tells us that there are many who cannot tolerate the side effects of antimuscarinic drugs, therefore the introducton of Mirabegron is a viable alternative treatment option. For those who are currently receiving Mirabegron for any other conditions where it proves benefical, should certainly continue with their treatment.
Section 2 (The technology)	Mirabegron may also prove to be an effective alternative treatment option for those suffering with other bladder conditions such as interstital cystitis or painful bladder syndrome, pelvic pain syndrome and any other conditions that require the bladder to relax therefore reducing discomfort and

	pain.
Section 3 (The manufacturer's submission)	The COB Foundation recognises that Astellas Pharma have provided ethical clinical data and research to support the use of Mirabegron.
Section 4 (Consideration of the evidence)	The impact of overactive bladder illness on an individuals life cannot be understated. Patients suffering with this life debilitating illness could be helped by the introduction of this medication. We therefore endorse the release of Mirabegron as a viable treatment option.
Section 6 (Proposed recommendations for further research)	The COB Foundation is a stakeholder and will be commenting on the development of these guidelines.
Section 7 (Related NICE guidance)	The COB Foundation is a support group for those suffering with debilitating bladder illness and would prefer that the review date be brought forward if possible.

Role	NHS Professional
Location	England
Conflict	no
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There is definitely a need for an alternative to anti muscarinic drugs.
Section 3 (The manufacturer's submission)	In section 3.40 it gives solifenacin 10mg a QALy 0f £340 but solifenacin 5mg £12493 is this right?