Appendix G -Professional organisation statement template

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal (STA)

Mirabegron for the treatment of symptoms associated with overactive bladder

Thank you for agreeing to give us a statement on your organisation's view of the technology and the way it should be used in the NHS.

Healthcare professionals can provide a unique perspective on the technology within the context of current clinical practice which is not typically available from the published literature.

To help you in making your statement, we have provided a template. The questions are there as prompts to guide you. It is not essential that you answer all of them.

Please do not exceed the 8-page limit.

About you

[redacted]

Name of your organisation: BAUS
Are you (tick all that apply):

-

- a specialist in the treatment of people with the condition for which NICE is considering this technology?
- a specialist in the clinical evidence base that is to support the technology (e.g. involved in clinical trials for the technology)?
- an employee of a healthcare professional organisation that represents clinicians treating the condition for which NICE is considering the technology? If so, what is your position in the organisation where appropriate (e.g. policy officer, trustee, member etc)?

Section of Female, Neurological & Urodynamic committee members

Appendix G -Professional organisation statement template

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal (STA)

Mirabegron for the treatment of symptoms associated with overactive bladder

What is the expected place of the technology in current practice?

As stated in the scope, the overactive bladder is a very common problem. The current treatment options are

1. **Bladder retraining**
2. **Medication**
3. **Intravesical Botulinum Toxin**
4. **Posterior Tibial Nerve Stimulation**
5. **Sacral Nerve Stimulation**
6. **Surgery**

The only current class of medication available are the anticholinergics, which are general in their actions (oxybutynin) or more urospecific and of a lower or higher dose. There are significant side effects with this class of drugs (dry mouth, constipation, heartburn) which limit it's use and in a significant number of patients it is not effective. The older patients, in which the incidence is higher, are more susceptible to the side effects. Currently the medication is used in the primary and secondary care setting. There are clinical guidelines as mentioned in the Scope.

Mirabegron is a beta 3 agonist which is the first alternative class of drug being introduced into clinical practice. It is not yet available in England and Wales.

Appendix G -Professional organisation statement template

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal (STA)

Mirabegron for the treatment of symptoms associated with overactive bladder

The advantages and disadvantages of the technology

"Mirabegron is the first beta 3 agonist which is being introduced into clinical practice. It has been shown to have similar efficacy to an active comparator, tolterodine, both in Phase II and Phase III studies. The efficacy of this agent in the trials where it has been studied has been lower than that seen in some antimuscarinic studies, but this has been attributed to the relatively mild symptoms in the population being studied and the key issue is that it had similar efficacy to the widely used antimuscarinic tolterodine. The side effect profile of this agent is different to that of antimuscarinics, with no significantly greater incidence of dry mouth, constipation or heartburn noted than placebo in the trials where it has been studied.

It has not been used in real life clinical practice in Europe but has been on the market in Japan with a license for the last year, and efficacy has been reported from there. A European Phase III long term study out to a year has been conducted, which has confirmed that there are no safety concerns and efficacy seems to be maintained. The major problem with interpreting the data is that none of the Phase II or Phase III studies have yet been published.

This agent introduces a new potential class of therapy for overactive bladder which may be beneficial in patients who don't achieve efficacy with an antimuscarinic or who are unable to tolerate antimuscarinic side effects. There is also potential for combination of a therapy such as this with an antimuscarinic, if necessary at lower doses of each agent, to therefore optimise the efficacy and safety profile. We must stress that there are no data published with regard to combination studies to date."

Any additional sources of evidence

Appendix G -Professional organisation statement template

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal (STA)

Mirabegron for the treatment of symptoms associated with overactive bladder

As stated above there is no published data. Submission of the phase 2&3 data by the company to the advisory committee would be essential to allow for specialist recommendations.

Implementation issues

Mirabegron would be prescribed in primary and secondary care. Education would be provided by secondary care specialist to general practitioners, once the specialist had gained experience with it.

Equality

There are no issues.