

Patient Interest Groups

Submission of Evidence Template

Product to which this submission relates	Duloxetine (Yentreve)
Date of SMC meeting (if known)	

NB Not all sections on this form are required to be completed.

Disclaimer: *The comments contained in this document are not those of the company (licence holder), nor of SMC and are the responsibility of the submitting group.*

Should you have any queries regarding the completion of this form,
please contact the SMC secretariat:

Telephone: 0141 225 6989/6997

Section 1 – General Information

Submitting Organisation

Please provide an overview of the organisation making the submission, including the aims of the organisation and an outline of membership.

Incontact is the UK organisation for people with continence problems. Uniquely, Incontact is run by and for consumers.

We offer support and information to service users, their carers and the health professionals who provide treatment. A central function of Incontact is to raise awareness amongst the public and health professionals of these common problems, and the range of treatment and management options available. We aim to break down the stigma that still surrounds continence problems.

We provide support to consumers through local support groups (27 in UK) online live chat sessions on our website, telephone support as well as producing literature for distribution throughout the UK.

“Our Vision”

A future where incontinence is no longer taboo, where people with bladder and bowel problems have free access to information and support and to the treatments, products and services they need.

Number of People Affected by this Disease

Although SMC has access to epidemiological data, you may wish to provide information on the number of people who are affected by the disease.

Hunskar – did research in UK, France, Germany & Spain on the prevalence of urinary incontinence for women over 18 – it was 32%

When broken down it stated that 16.8% had stress incontinence.

In the UK prevalence of Urinary incontinence for women living at home is estimated at between 8 and 14% - for those aged 45-64 and 10-20% for those aged 65 and over.

Stress incontinence, the most common form (more than half of women who suffer from incontinence have Stress Urinary Incontinence), peaks in middle aged (40-49) while urge incontinence peaks in the elderly. Mixed incontinence increases with age.

Stress incontinence is ‘under reported’ and ‘under treated’. Most women with urinary incontinence do not seek medical help says Dr Deborah Lightner (Mayo School of Medicine, USA) told the EAU symposium Madrid March 2003.

User Perspective

Please provide an outline of user needs, preferences or experiences in relation to the use of existing medication/treatments.

At present the accepted treatment for patients with stress urinary incontinence is:

- Pelvic Floor Muscle Exercises:
- Electro-stimulation treatment from a physiotherapist
- Surgery - colposuspension, TVT or TOT

This process involves:

- Referral to a physiotherapist/continence advisor – sometimes a waiting list of considerable time before being seen and assessed – invasive digital examination in order to assess pelvic floor and then ensure patient knows how to do the exercises.
- Usually a period of 3months of doing exercises at home before further check-up.
- If exercises have been unsuccessful a course of electro-stimulation may be carried out.
- If no improvement is obvious patient will then be referred to urology department. Usually there is a waiting list to see the urologist.
- Further tests and investigations which are generally embarrassing and invasive.
- Further consultation before a decision of surgery may be agreed.
- Waiting time for surgery
- This is a very lengthy process.

During this time the patient is deflated that nothing is working, her condition and quality of life is deteriorating. Emotional well being and relationships can be affected greatly.

To have the opportunity of choosing a medication as a first line treatment would be welcomed by most patients while waiting for referral to physiotherapist or continence advisor to have pelvic floor assessment carried. Some patients may prefer not to have invasive examination. At this point there will be the opportunity of doing pelvic floor exercises along with the medication and a better chance that no further referral would be required.

If referral is still required the patient at least knows they are being given the chance of their condition being improved while they are waiting to be seen by an appropriate consultant. It is anticipated that this course of action would help increase the patient's quality of life, and allow her to lead as normal a life as is possible.

Quality of life means different things to different people.

Eg. 1. An elderly lady who is at home, able to manage to the toilet to change herself, has the facilities and ability to change and wash her clothes when she has an accident may feel that her quality of life is acceptable even though she may have 5/6 episodes of incontinence daily.

Eg. 2. The young women who's working as a teacher and has an accident during teaching can have her confidence dented severely by just one or two episodes a week. The effect of this can effectively make her condition worse – she will go to the toilet at ever opportunity to try to prevent such an episode, she cuts down on her fluids – this in turn causes her to have frequency, urinary infections, shrinking of her bladder thus ending up with mixed incontinence. A vicious circle then begins, she avoids going out socially she is irritable, unable to cope with work, time off sick, relationship difficulties and so on. The personal cost is immense. The cost to the country should also be considered, as a replacement is required to carry out her job, she will be receiving sickness benefit, very likely be commenced on anti-depressant medication, as well as require products to contain her leaking.

Section 2 – Product Specific Details

Potential Impact

Please provide an outline of the potential impact upon the lives of patients/carers in relation to the product to be assessed.

Bladder incontinence affects every aspect of life. It causes:

- embarrassment
- humiliation

- anxiety
- depression
- Isolation
- Relationship difficulties
- Quality of life can become very poor

The waiting time to be diagnosed and then be given the correct treatment can be a very long process and those who are living with continence issues often have a horrendous time obtaining the treatment most suitable for them.

Although I have no researched evidence, it is my experience that over 60% of people who admit to having a continence issue and eventually ask for help from Incontact are on prescribed medication for depression.

Education and awareness of continence issues continue to improve but if women realised that there was the possibility that their condition may be helped/cured by a prescribed medication they may come forward for treatment at a much earlier stage. That may have an impact on health care services in the short term but would mean that women are treated earlier, receive the correct advice on pelvic floor exercises and will hopefully prevent more serious problems in later life. The monetary cost in the long run would be less and the impact on patients' quality of life could be immense.

Perceived Advantages/Disadvantages

Please provide an outline of the perceived advantages or disadvantages in relation to this product or its mode of delivery.

Duloxetine could be used as a first step option with marked improvements in patient's condition.

It can be used in conjunction with Pelvic floor exercises to ensure the best possible results

It can be reduced or stopped when condition improves

It could prevent patients quality of life becoming unbearable as it may prevent condition worsening while waiting for further investigation and may lessen the need for surgery

The disadvantages of using Duloxetine may be that the patient can suffer from transient nausea.

Long term complications may occur – as this is a new drug it is too early to say that no long term problems may affect the patient. All patients given the opportunity of taking the medication should have this explained to them and given the choice.

Wider Implications

Please provide any further details in relation to the wider implications for patients or carers (eg reduced hospitalisation, reduced time off work, quality of life issues).

Wider implication on patients include:

- A better uptake to receiving professional help
- Improved quality of life in short term and long term
(many of our elderly people who are being treated with pads and medications are very likely to have sought treatment earlier if they had been aware of a simple treatment for this condition. They would then have been made more aware of how to manage/treat the condition thus avoiding long term incontinence in old age.

Management of incontinence in the elderly has huge financial implications on this NHS. Much of this could have been avoided with early treatment, education and management.

Many of our elderly are in care/nursing homes because they and/or their carers could not cope with dealing with bladder incontinence in their home. It is my opinion that much of this could have been avoided if they had received treatment at an early stage in their life.

- Young women and menopausal women with SUI will come forward at a much earlier stage, if they know that there is the possibility that they can be helped immediately by medication and good management.

The impact on people with SUI who develop depression and other mental health issues can be huge – this can perhaps be avoided with early successful treatment.