

# Considered Judgement Form

*This form is a checklist of issues that may be considered by the Purchasing Guidance Advisory Group when making purchasing recommendations.*

**Meeting date:** 24 March 2005

**Topic:** Evidence based review of medicines for sexual dysfunction in females

## Background and Purpose:

ACC is occasionally asked to fund sexual dysfunction medicines for female claimants in cases where the claimant's sexual problems are believed to result from a physical injury they have suffered. However, use of such drugs to treat women is controversial; the evidence base is believed to be poor, and drug companies have been accused of inappropriately medicalising the complex nature of women's sexual problems in order to create a new market for their products.

Sunita Goyal (Pharmaceutical Advisor, Healthwise) has therefore asked the Evidence Based Healthcare Advisory Group to commission a review to identify what, if any, evidence is available to support the use of the following medicines in women experiencing sexual dysfunction caused by physical injury:

- The oral PDE5 inhibitors tadalafil (Cialis<sup>®</sup>), vardenafil (Levitra<sup>®</sup>), and sildenafil (Viagra<sup>®</sup>)
- Sublingual apomorphine (Uprima SL)

The review has been carried out by New Zealand Health Technology Assessment (NZHTA), a research unit of the University of Otago.

## 1. Effectiveness, Volume of Evidence, Applicability /Generalisability and Consistency

Few good quality studies evaluating the efficacy and safety of the specified medicines for female sexual dysfunction were found. Only one study met the criteria for inclusion in the evidence tables.

From the available studies, there is no evidence that tadalafil or vardenafil are effective and safe treatments for female sexual dysfunction. There is limited evidence that sildenafil (3 studies), sublingual apomorphine (1 study), or indeed any other pharmacological products are effective and safe treatments for female sexual dysfunction. In fact in 2004, after clinical trials involving 3,000 women failed to demonstrate conclusive results, Pfizer announced that it was no longer seeking regulatory approval for sildenafil as a treatment for female sexual dysfunction.

The author found no substantive evidence in terms of clinically significant outcomes to support the use of any of the specified medicines for the treatment of women with sexual dysfunction due to physical injury.

## 2. Cost

Given the lack of evidence of effectiveness, a discussion of cost effectiveness was felt to be premature.

<b>3. Clinical impact</b>
<b>4. Equity, Maori/Pacific Health, Acceptability</b>
<b>5. Possible Purchasing Options</b>
<ul style="list-style-type: none"> <li>• Don't purchase</li> <li>• Don't purchase at this stage, but review the decision when new evidence becomes available</li> <li>• Purchase subject to special controls (case-based approval)</li> <li>• Purchase</li> </ul>
<b>6. Evidence Statement</b>
<p><b><u>Evidence statements:</u></b></p> <p>There is no evidence that tadalafil or vardenafil are effective and safe treatments for sexual dysfunction in women.</p> <p>There is limited evidence that sildenafil or sublingual apomorphine are effective and safe treatments for sexual dysfunction in women. Pfizer, the sponsor for sildenafil, is no longer seeking registration for the product as a treatment for female sexual dysfunction.</p> <p>No substantive evidence in terms of clinically significant outcomes is currently available for the effectiveness of any of these medicines in the treatment of women experiencing sexual dysfunction due to physical injury.</p>
<b>7. Purchasing Recommendations</b>
<p><b><u>Purchasing recommendation:</u></b></p> <p>Do not purchase, but review the decision when new evidence becomes available.</p>

## Glossary

### 1. Effectiveness, Volume of Evidence, Applicability /Generalisability and Consistency

Comment here on:

- the extent to which the service/product/ procedure achieves the desired outcomes. Specific reference needs to be made to safety. Report number needed to treat and harm where possible,
- any issues concerning the quantity of evidence and its methodological quality and the extent to which the evidence is directly applicable or generalisable to the New Zealand Population,
- the degree of consistency demonstrated by the available evidence.

Where there are conflicting results, indicate how the group formed a judgement as to the overall direction of the evidence

### 2. Cost

Comment on:

- any economic costs associated with this service, product or procedure

### 3. Clinical impact

Comment on:

- the clinical impact eg size of population, magnitude of effect, relative benefit over other management options, resource implications, balance of risk and benefit

### 4. Equity, Maori/Pacific Health, Acceptability

Comment on the extent to which:

- the service, product or procedure reduces disparities in health status (equity of access, resources, health outcome),
- is consistent with the treaty of Waitangi and encourages Maori/ Pacific participation in providing and using service, product and procedures, and
- is consistent with values and expectations of New Zealanders.

### 5. Purchasing Options

List the possible purchasing options.

### 6. Evidence Statement

Summarise the advisory group's synthesis of evidence relating to this service, product or procedure, taking the above factors into account, and indicate the evidence level that applies.

### 7. Recommendations

What recommendation(s) does the advisory group draw from this evidence?