APPENDIX 5

Melatonin for sleep onset difficulties in Children and Adolescents

(Information for parents and carers)

Sleep disorders in children and adolescents include problems getting to sleep or staying asleep. Sleep disorders are more common in children with developmental problems and disabilities as they can be more persistent and difficult to treat. Improving sleep patterns leads to a general improvement in health, behaviour and well-being.

Melatonin is a hormone found naturally in the body to help regulate a person's sleep pattern. Normally, melatonin levels begin to rise in the mid to late evening, remain high for most of the night, and then drop in the early morning hours. Changes in the times when we go to bed and when we get up can affect when melatonin is produced.

Evidence has shown that taking melatonin increases sleep time by only 20 minutes and reduces the time taken to fall asleep by approximately 20 minutes. There are also ongoing concerns over the lack of long-term safety data in children.

Melatonin has been shown to be of benefit in children who:

- are blind
- have learning disabilities
- have neurological/neurodevelopmental disorders.

The main remedy for children and young people with sleep disorders are non-drug treatments, which include good sleep hygiene. Good sleep hygiene includes day-to-day things that can be done at home to help children and young people sleep, such as having fixed times for going to bed and getting up; keeping the bedroom comfortable; relaxing before going to bed; and avoiding TV, computer games and high levels of excitement for at least an hour before bedtime.

When appropriate behavioural sleep interventions fail, Melatonin may be used to help children get into a regular sleep pattern.

There are a range of licensed melatonin products in the UK, however, currently none of the melatonin products are licensed for sleep onset difficulties in children, therefore they are used 'off-label'.

The most common side-effects reported in those taking melatonin are headache, hyperactivity, dizziness and abdominal pain. There are no reports of melatonin causing serious side effects. Based on a small number of studies, melatonin appears relatively safe in the short-term to medium-term; however, there are still ongoing concerns over the lack of long-term safety data in children.

There is no information on the safety of use in pregnancy and so melatonin **should not** be used in pregnancy.

How to take Melatonin

The starting dose will be 3mg, given to the child 30 minutes before the child's bedtime. The medicine should be given at about the same time each day so that it becomes part of the child's daily routine. This is continued for one or two weeks.

To monitor effectiveness, it is important to use the sleep diaries provided, and continue to follow the sleep behavioural advice.

If this dose has little or no effect, it may be increased to 6mg (or occasionally 9mg) at night for a further 3 weeks. If an improvement is seen, a further 6 months (a maximum of 2 monthly prescribed at a time) of treatment will be prescribed to help the child establish a better sleep pattern. After this, a trial without melatonin treatment will be needed. For most children the melatonin will simply be stopped.

For children who have difficulties in swallowing, some brands of melatonin tablets can be crushed and mixed with a small drink or soft food. Ask your pharmacist for advice.

If the child is sick (vomits) less than 30 minutes after taking the dose of melatonin, give them the same dose again; if it is more than 30 minutes after taking the dose, they do not need another dose.

If you forget to give the dose and the child is asleep, wait until the next evening and give the normal dose as usual.