MEDICINES ASSESSMENT ADVISORY COMMITTEE (MAAC)
REPORT ON THE EVALUATION OF THE PRECLINICAL
AND CLINICAL DATA OF A NEW MEDICINE APPLICATION

11 May 2009

ASSESSOR: [redacted]

PRODUCT: Sativex

ASSESSMENT

This is the second time that we have responded to the application for Sativex in regard to its use for the relief of neuropathic pain and spasticity in multiple sclerosis and also for the relief of pain in advanced cancer. This has been a very controversial submission, under Section 23 application! Having said that, I note that in the original consideration on 18/03/08 it was as a new medicine application under Section 21. G W Pharmaceuticals have responded somewhat tersely in a letter to MAAC on 21/11/08. They have taken exception to some of our interpretation, particularly in relation to Study GWMS0107. They have also re-included the report by [redacted] from the Centre of Statistics and Medicine regarding the assessment of blinding in Phase 3 Sativex Spasticity Studies. His conclusion is that there is no evidence to suggest that the blinding has been seriously compromised in the three studies. Also if any subjects did become unblinded then there is no evidence in these three studies of any bias in the assessment of the treatment difference between Sativex and placebo for efficacy, adverse events or study drug dosing. That therefore, I think, answers the committee's concerns regarding the statistical validity.

In response to providing further data from ongoing studies, we have been provided with an overview of the results from GWMS0501 which is a double-blind randomised placebo-controlled parallel group study of Sativex when added to the existing treatment regime in the relief of central neuropathic pain in subjects with multiple sclerosis. A positive response has been demonstrated; however, it is not statistically significant against placebo (50% vs 45%). The 45% is a very high placebo response and is thought to be related to the higher frequency of spray administration per day. The responses for those taking <8 sprays per day are at greater variance (27% vs 13%), and for those taking <12 sprays per day 43% vs 30%. Therefore, if the study protocol had been amended to only those patients taking <12 sprays per day it would have reached statistical significance (p=0.003).

Conclusion

My viewpoint in regard to the use of the Sativex application remains the same. I do think there is a place for its use under Section 23 in a very limited patient group. No doubt further clinical information will come to hand in the not too distant future.