19/11/2009

Quality Review Final

An application for the new medicine Sativex (oromucosal spray) was made by GW Pharma on 7 January 2008. Sativex is notable in that it is the first medicine containing the active components tetrahydrocannibanol and cannibanol.

The National Drugs Policy Unit of the Ministry of Health were supportive of GW Pharma in making this application having identified a place for such a medicine; primarily in palliative care situations. On this basis a request for priority assessment was requested by the MOH and subsequently granted by Medsafe.

Medsafe began evaluation of the pharmaceutical and clinical portions of the application in March 2008. The pharmaceutical evaluation was straightforward and all issues have been resolved with the exception of finalised labels. Being a controlled drug there is a requirement to state the clinical indications on the label and therefore labels can only be finalised once a final decision on the product is made.

Clinical evaluation occurred in two parts. The initial clinical evaluation was undertaken by the MAAC in keeping with MAAC procedures of the time. The MAAC deferred a recommendation and requested further information. This further information was received by Medsafe on the 1st of December 2008. Due to a change in MAAC procedures this data did not go directly back to the MAAC for consideration. Rather, the primary and secondary evaluators assessed the further data and made their recommendations directly to Medsafe. Their reports have been peer reviewed and Medsafe's final clinical recommendation on this product was:

- That a recommendation to approve the indications "relief of cancer pain" and "relief of neuropathic pain" **could not be made**.
- That a recommendation to approve the indication "relief of spasticity in MS" **could be made under section 23**, although the Peer reviewer notes that the two external evaluators were divided in opinion on this matter and recommended review by the MAAC.

Conclusion:

It is clear from the evaluation reports that there is an absence of conclusive data on the efficacy of this product. Approval under section 23 has been requested by the applicant and therefore increased importance on the relative risk:benefit profile of the product, particularly in the patient population concerned is an important consideration. Nonetheless, this application should be referred to the MAAC as a definitive recommendation to approve this product has not been reached.

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